EXHIBIT 17

REDACTED
Order Granting in Part and Denying in Part Motions for Class Certification

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE HIV ANTITRUST LITIGATION

Case No. 19-cv-02573-EMC

FILED UNDER SEAL

ORDER GRANTING IN PART AND DENYING IN PART MOTIONS FOR CLASS CERTIFICATION

Docket Nos. 692, 694

United States District Court
Northern District of California

Currently pending before the Court in this antitrust case are two motions for class certification as well as related *Daubert* motions to exclude expert testimony. The motions for class certification have been filed by (1) the End-Payor Plaintiffs ("EPPs"), *i.e.*, the indirect purchasers, and (2) the Direct Purchaser Plaintiffs ("DPPs"). Having considered the parties' briefs and accompanying submissions, as well as the oral argument of counsel, the Court hereby **GRANTS** in part and **DENIES** in part the EPP motion for class certification and **GRANTS** in part and **DENIES** in part the DPP motion. The Court also **DENIES** the *Daubert* motions related to Ms. Craft, Dr. Frank, and Dr. Lamb.

I. FACTUAL & PROCEDURAL BACKGROUND

The EPPs and DPPs allege that two pharmaceutical companies, Gilead and Janssen,[1] have engaged in anticompetitive conduct designed to stave off competition from generic manufacturers. There are three categories of alleged anticompetitive conduct. A fuller discussion of that conduct

[1] With the approval of the Court, the EPPs settled their dispute with a third pharmaceutical company, BMS. The DPPs have also settled their dispute with BMS, but final approval on that settlement has not yet taken place.

can be found in the Court's prior order of March 3, 2020. *See Staley v. Gilead Scis., Inc.*, 446 F. Supp. 3d 573 (N.D. Cal. 2020). Below, however, is a brief summary.

(1) Gilead entered into patent settlement agreements with Teva, a generic manufacturer. Under those agreements, Teva agreed to delay entry into the market with generic drugs that would compete with Gilead's brand drugs Viread (TDF), Truvada (TDF/FTC), and Atripla (TDF/FTC/EFV). In exchange, Teva was given most-favored-entry and most-favored-entry-plus ("MFE" and "MFEP," respectively) provisions. "The MFE/P guaranteed Teva that no other generic [manufacturer] could enter [the market] before it, even via a litigation victory invalidating the patents, and that Gilead would not grant any other manufacturer a license to enter the market until 180 days after Teva launched." EPP Mot. at 2 (noting that the latter essentially resurrected the 180-day exclusivity that Teva once had as the first ANDA filer (with respect to Truvada and Atripla) but then forfeited).

(2) Gilead and Janssen, as well as Gilead and BMS, entered into agreements that contained No-Generics Restraints ("NGRs").[2] The NGRs were basically noncompete provisions. Essentially, two companies – such as Gilead and Janssen – would contract to produce a fixed-dose combination ("FDC") drug. That FDC would be made up of (1) the first company's brand drug that was due to lose its patent protection and (2) the second company's brand drug that had a longer life in terms of patent protection. The two companies would then agree that, even after the first company's brand drug *lost* its patent protection, the second company would not then sell a FDC consisting of its own brand drug and a generic version of the first company's brand drug. *See* EPP Mot. at 5 (stating that the NGRs "prohibit[ed] the parties from making competing (and cheaper) versions of [the]

[2] Although the EPPs and DPPs have settled their disputes with BMS, that does not bar the EPPs and DPPs from asserting as part of their cases that Gilead still bears liability for entering into allegedly anticompetitive agreements with BMS.

fixed-dose combinations . . . using generic components"). This agreement effectively protected the first company's brand drug from generic competition even after any patent protection for that drug expired. Some of the agreements with NGRs protected Gilead's drugs that were about to lose patent protection (*e.g.*, TDF, FTC, and TDF/FTC), and some of the agreements protected Janssen or BMS's drugs that were about to lose patent protection.

(3) Gilead intentionally delayed the development of TAF (a NRTI "backbone" drug) "until generic TDF was imminent" and then "us[ed] anticompetitive tactics to switch its TDF franchise to TAF (including to products protected by the No-Generics Restraints)." EPP Mot. at 7.

Based on the above, the EPPs have asserted federal antitrust claims, state antitrust claims, and state consumer protection claims. The DPPs have asserted federal antitrust claims.

II. LEGAL STANDARD

A. Class Certification

Federal Rule of Civil Procedure 23 governs class actions. Rule 23(a) provides as follows:

> One or more members of a class may sue or be sued as representative parties on behalf of all members only if:
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> (1) the class is so numerous that joinder of all members is impracticable;
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> (2) there are questions of law or fact common to the class;
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> (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and
>
> (4) the representative parties will fairly and adequately protect the interests of the class.

Fed. R. Civ. P. 23(a).

Rule 23(b) goes on to provide in relevant as follows:

> A class action may be maintained if Rule 23(a) is satisfied and if:
>
> . . . .
>
> (2) the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate

respecting the class as a whole; or

(3) the court finds that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy. The matters pertinent to these findings include:

(A) the class members' interests in individually controlling the prosecution or defense of separate actions;

(B) the extent and nature of any litigation concerning the controversy already begun by or against class members;

(C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and

(D) the likely difficulties in managing a class action.

Fed. R. Civ. P. 23(b).

Essentially, for a class to be certified, the plaintiff must meet the Rule 23(a) requirements and one of the Rule 23(b) requirements. Rule 23(b)(2) is applicable where the class seeks injunctive relief; Rule 23(b)(3) is applicable where the class seeks damages.

The Supreme Court has emphasized that a rigorous analysis is required at class certification. *See, e.g.*, *Comcast Corp. v. Behrend*, 569 U.S. 27, 33 (2013) (internal quotation marks omitted). The Ninth Circuit has given more precision to this standard, holding that, to prevail at class certification, "plaintiffs must prove the facts necessary to carry the burden of establishing that the prerequisites of Rule 23 are satisfied *by a preponderance of the evidence*." *Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC*, 31 F.4th 651, 665 (U.S. 9th Cir. 2022) (emphasis added); *cf. In re Lidoderm Antitrust Litig.*, No. 14-md-02521-WHO, 2017 U.S. Dist. LEXIS 24097, at *38 (N.D. Cal. Feb. 21, 2017) (asking whether a case is "more appropriate for class certification than not"). "In carrying the burden of proving facts necessary for certifying a class . . . , plaintiffs may use any admissible evidence." *Olean*, 31 F. 4th at 665.

Expert opinion may be submitted in conjunction with a motion for class certification, either by the plaintiff or the defendant. A court may have to determine whether expert opinion is admissible in the first place under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). If both sides have offered admissible expert opinions, then the court may have to weigh those opinions if they are conflicting. *See id.* at 666 ("The determination whether expert evidence

is capable of resolving a class-wide question in one stroke may include '[w]eighing conflicting expert testimony' and '[r]esolving expert disputes,' where necessary to ensure that Rule 23(b)(3)'s requirements are met and the 'common, aggregation-enabling' issue predominates over individual issues."); *see also In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 322-24 (3d Cir. 2008) (cited approvingly in *Olean*; stating that "opinion testimony should not be uncritically accepted as establishing a Rule 23 requirement merely because the court holds the testimony should not be excluded, under *Daubert* or for any other reason" – rather, a court must consider expert testimony and give it whatever weight the court deems appropriate, although "[a] court's determination that an expert's opinion is persuasive or unpersuasive on a Rule 23 requirement does not preclude a different view at the merits stage of the case").

Certification analysis may overlap with the merits of a plaintiff's underlying claim, *see Comcast*, 569 U.S. at 33, but "Rule 23 grants courts no license to engage in free-ranging merits inquiries at the certification stage. Merits questions may be considered to the extent – but only to the extent – that they are relevant to determining whether the Rule 23 prerequisites for class certification are satisfied." *Amgen v. Conn. Ret. Plans & Tr. Funds*, 568 U.S. 455, 466 (2013).

B. *Daubert*

As indicated above, class certification proceedings may involve *Daubert* challenges to expert opinions.

> [Federal] Rule [of Evidence] 702 lays out the requirements for a district court to admit expert testimony. The rule provides that a witness "qualified as an expert by knowledge, skill, experience, training, or education," Fed. R. Evid. 702, may offer opinion testimony if it "rests on a reliable foundation and is relevant to the task at hand,'" *Daubert*, 509 U.S. at 597.

United States v. Nelson, 533 F. Supp. 3d 779, 787 (N.D. Cal. 2021). The full text of Rule 702 is provided below.

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;
(c) the testimony is the product of reliable principles and methods; and
(d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

With respect to (c) above, reliability

> requires that the expert's testimony have "a reliable basis in the knowledge and experience of the relevant discipline." The district court must assess whether "the reasoning or methodology underlying the testimony is scientifically valid" and "properly can be applied to the facts in issue," with the goal of ensuring that the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." "The test 'is not the correctness of the expert's conclusions but the soundness of his methodology,' and when an expert meets the threshold established by Rule 702, the expert may testify and the fact finder decides how much weight to give that testimony."
>
> The reliability analysis is "a malleable one tied to the facts of each case," and "district courts are vested with 'broad latitude' to 'decide how to test an expert's reliability' and 'whether or not an expert's relevant testimony is reliable.'" Although *Daubert* identifies several factors that may be used for evaluating the reliability of an expert – whether the scientific theory or technique has been tested, peer reviewed, identified as having a particular rate of error, and generally accepted in the scientific community – district courts are not required to consider all (or even any) of these factors, nor are they required to hold a "*Daubert* hearing."

United States v. Ruvalcaba-Garcia, 923 F.3d 1183, 1188-89 (9th Cir. 2019).

Reliability is also implicated in (d) above. With respect to (d), the 2000 Advisory Committee Notes for Rule 702 comment as follows:

> The amendment specifically provides that the trial court must scrutinize not only the principles and methods used by the expert, but also whether those principles and methods have been properly applied to the facts of the case. As the court noted in *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994), "any step that renders the analysis unreliable . . . renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology."

Fed. R. Evid. 702, 2000 Advisory Committee Notes (emphasis omitted); *see also* McCormick on Evid. § 15 (stating that "[a] misapplication of the methodology can result in a flawed conclusion").

III. EPP MOTION FOR CLASS CERTIFICATION

As noted above, pending before the Court are two motions for class certification: one filed by the EPPs and one filed by the DPPs. The Court addresses the EPP motion first.

A. Class Definitions

The EPPs move for certification of three Damages Classes and three Injunctive Relief Classes.

- Damages Classes: (1) the Truvada Class; (2) the Atripla Class; and (3) the Complera Class.[3]
- Injunctive Relief Classes: (1) the Evotaz Class; (2) the Prezcobix Class; and (3) the cART Foundation Drug Class.[4]

The Damages Classes are made up of third-party payors ("TPPs") only (*i.e.*, not individual consumers); the Injunctive Relief Classes are made up of both TPPs and consumers.

With respect to the Damages Classes, the Truvada and Atripla Classes are each defined as follows: TPPs in the United States that indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of (1) the brand drug and/or (2) its AB-rated generic equivalent sold by Teva in the "Specified States" during the period February 1, 2018, through the date of the order certifying the class.

The "Specified States" are the 35 states that have repealed *Illinois Brick v. Illinois*, 431

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[3] Truvada = TDF/FTC (Gilead drug).

Atripla = TDF/FTC/EFV (Gilead/BMS drug).

Complera = TDF/FTC/RPV (Gilead/Janssen drug).

[4] Evotaz = ATV/COBI (BMS/Gilead drug).

Prezcobix = DRV/COBI (Janssen/Gilead drug).

cART Foundation drugs = TDF/FTC/EFV (Gilead/BMS drug); Biktarvy (BIC/TAF/FTC) (Gilead drug); Complera (TDF/FTC/RPV) (Gilead/Janssen drug); Descovy (TAF/FTC) (Gilead drug); Genvoya (TAF/FTC/EVG/COBI) (Gilead/Japan Tobacco drug); Odefsey (TAF/FTC/RPV) (Gilead/Janssen drug); Stribild (TDF/FTC/EVG/COBI) (Gilead/Japan Tobacco drug); Symtuza (TAF/FTC/DRV/COBI) (Gilead/Janssen drug); Truvada (TDF/FTC) (Gilead drug); and Viread (TDF) (Gilead drug).

U.S. 720 (1977), which thus enables an indirect purchaser to seek damages.[5] *See* EPP Mot. at 11. 15, 17 & n.11 (listing 35 states); *Stromberg v. Qualcomm Inc.*, 14 F.4th 1059, 1064 (9th Cir. 2021) (noting that "the Supreme Court has long held that indirect purchasers – meaning those who purchase the relevant product through middlemen – are barred from seeking damages for alleged Sherman Act violations"; adding that, "[c]urrently, thirty-five states and the District of Columbia effectively repealed *Illinois Brick* . . . in one form or another, but fifteen states have not"). February 1, 2018, is the date the EPPs contend a generic version of TDF/FTC should have been available. *See* EPP Mot. at 4 (arguing that Teva would have entered the market as early as February 2018 but for the allegedly anticompetitive settlement agreement with Gilead).

The Complera Class has a similar definition (other than the generic/Teva component): TPPs in the United States that indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of the brand drug in the Specified States during the period February 1, 2018, through the date of the order certifying the class. The Complera Class makes no reference to generic drugs or Teva because, as of yet, there is no generic version of Complera available.

As for the Injunctive Relief Classes, they are each defined as follows: Persons or entities in the United States who indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of the brand drug(s) for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, during the period May 14, 2015 through the date of final judgment in the case.

B. Rule 23(a) Requirements

For both the Damages Classes and the Injunctive Relief Classes, the Rule 23(a) requirements must be met. As noted above, the Rule 23(a) requirements are: numerosity, commonality, typicality, and adequacy.

1. Numerosity and Commonality

The EPPs have easily met the numerosity and commonality requirements. Defendants do

[5] Although the EPPs have identified 35 states in their motion, the Court notes that the state law claims in the operative pleading do not seem to implicate all 35 states. *See, e.g.*, FAC (in Count 5, conspiracy to monopolize in violation of state antitrust laws, identifying the laws of 29 states, and in Count 11, violation of state consumer protection laws, identifying the laws of 23 states).

not seriously dispute otherwise. Even if Defendants had, that position would lack merit. For example, for the Damages Classes, the number of TPPs is significant – "in the hundreds (for Complera) [and] thousands (for each of Atripla and Truvada)." EPP Mot. at 18 (citing Craft Expert Rpt. ¶ 47 & Table 11). Therefore, joinder would not be practicable. As for commonality, there are clearly common questions of law or fact for each Damages Class and each Injunctive Relief Class – *e.g.*, whether the Teva patent settlement agreement (related to Truvada and Atripla) was anticompetitive, whether the NGRs in the various agreements between Gilead and either Janssen or BMS were anticompetitive, and whether Gilead's development/commercialization of TAF was anticompetitive.[6]

2. Typicality and Adequacy

For typicality and adequacy, Defendants do make challenges, but, for the reasons discussed below, these requirements have also been met.

a. Where Purchases or Reimbursements Made

Because BCBSA has been dismissed from the litigation,[7] the EPPs are left with four proposed class representatives for the Truvada Class (Teamsters, FOP, Local 1, and Pipe Trades) and one proposed class representative for the Atripla and Complera Classes (Teamsters). *See* Docket No. 991-3 (amendment). Defendants note that these "proposed representatives purchased or reimbursed for class products in only a fraction of the 35" *Illinois Brick* repealer states. Opp'n at 3. According to Defendants, the proposed representatives are typical/adequate (or have standing) only with respect to the states where they *actually* made purchases or reimbursements. *See* Opp'n at 4 ("Because the named EPPs did not reimburse for Truvada in 26 of the states, Atripla in 32 states, and Complera in 34 states, EPPs' damages claims in those states must be dismissed due to the named EPPs' lack of typicality and adequacy to represent class members where they made no reimbursements, and/or their lack of Article III standing.").

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[6] Contrary to what Defendants have suggested, the EPPs have not abandoned the TAF development/commercialization theory.

[7] Although the EPPs have filed a motion for leave to file a motion for reconsideration with respect to BCBSA, the Court has not yet ruled on that motion.

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The Court is not persuaded. As discussed below, the Court ultimately agrees with Defendants that which state's law applies depends on where a purchase or reimbursement was made – *e.g.*, California law applies where a purchase or reimbursement was made in California, but New York law applies where a purchase or reimbursement was made in New York. However, as this Court previously held in a different case, (1) "whether a plaintiff can bring claims on behalf of unnamed plaintiffs under the laws of states in which the named plaintiff does not reside or was injured is a matter of typicality, adequacy, and predominance under Rule 23, not Article III standing," and (2) whether a named plaintiff "'can adequately represent unnamed class members with claims under other states' laws *depends on how variable the laws are*'" – *e.g.*, "'[i]f the laws are similar enough, or if they can be grouped into a small number of categories with named plaintiffs representing each category, it may be unnecessary to have a named plaintiff from every state.'" *Sultanis v. Champion Petfoods U.S. Inc.*, No. 21-cv-00162-EMC, 2021 U.S. Dist. LEXIS 145293, at *21-22 (N.D. Cal. Aug. 3, 2021) (emphasis added).

This Court's ruling in *Sultanis* is not contrary to Ninth Circuit law. For example, in *Mazza v. American Honda Motor Co.*, 666 F.3d 581 (9th Cir. 2012), the Ninth Circuit indicated that a nationwide class applying California law could not be certified but left open whether there could be certification of a "smaller class containing only those who purchased or leased [certain vehicles] in California, *or [certification of] a class with members more broadly but with subclasses for class members in different states, with different jury instruction for materially different bodies of state law*." *Id.* at 594 (emphasis added). And other district courts in the circuit have also followed the same approach as this Court did in *Sultanis*. *See, e.g., Lidoderm*, 2017 U.S. Dist. LEXIS 24097, at *111 (noting that "[n]umerous courts in this District have certified cases involving indirect purchaser claims under different state laws"; "[t]he differences in the applicable state laws identified by defendants do not appear to be material or even significant").

Defendants' reliance on *Hawkins v. Comparet-Cassani*, 251 F.3d 1230 (9th Cir. 2001), is unavailing. *See id.* at 1238. There, the plaintiff was a convicted prisoner and challenged the use of stun belts on prisoners appearing in Los Angeles County courts. The district court granted him class representative status over both convicted prisoners *and* nonconvicted prisoners. On appeal,

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the Ninth Circuit held that certification was defective because the plaintiff

> presents some claims that are not typical of all class members: He raises an Eighth Amendment claim, which is reserved for "those convicted of crimes" and therefore would not apply to pre-trial detainees. As a convicted prisoner, Hawkins himself cannot bring a Fourth Amendment claim, which applies only to those not yet convicted. A named plaintiff cannot represent a class alleging constitutional claims that the named plaintiff does not have standing to raise. It is not enough that the class members share other claims in common.

Id. at 1238. As indicated by the above, *Hawkins* presents a markedly different scenario from that before the Court in the instant litigation. In *Hawkins*, the plaintiff had standing to bring a specific constitutional claim (based on the Fourth Amendment) but sought to represent unnamed class members whose rights were governed by an entirely different constitutional provision (the Eighth Amendment) that involved a different legal standard. In contrast, in the case at bar, the proposed class representatives and the unnamed class members are all bringing the same kind of claims – antitrust and/or consumer protection – even if based on the laws of multiple states. Where those claims are similar, typicality and adequacy may be satisfied.

Accordingly, in the instant case, the Court holds that, so long as the proposed class representatives' state antitrust and/or consumer protection claims are sufficiently similar to the antitrust and/or consumer protections claims of the other repealer states, the typicality and adequacy requirements of Rule 23(a) will be met. Because this same issue arises as part of the predominance inquiry for Rule 23(b)(3), the Court addresses it below. *See* Part III.C, *infra*.

b. <u>Local Government Entities</u>

Defendants' remaining challenge to typicality and adequacy concerns local government entities. Defendants point out that the EPPs have defined both the Damages Classes and the Injunctive Relief Classes to *exclude* all federal and state government entities but to *include* "cities, towns, municipalities or counties with self-funded prescription drug plans." EPP Mot. at 12 n.37. Defendants question whether it is appropriate for the proposed class representatives here – private actors – to represent local government entities.

As an initial matter, the Court notes that there do not appear to be any Eleventh Amendment/sovereign immunity concerns with respect to including local government entities in

the classes. *See Pittman v. Ore.*, 509 F.3d 1065, 1071 (9th Cir. 2007) ("As the Supreme Court has applied the Eleventh Amendment, 'an unconsenting State is immune from suits brought in federal courts by her own citizens as well as by citizens of another State.' Municipalities, in contrast, are not entitled to sovereign immunity in federal court."). Hence, there is a basis for distinguishing municipalities from states.

As to whether the proposed class representatives are capable of representing local government entities, Defendants have suggested that prior approval must be obtained before such entities can be represented by private (as opposed to government) counsel. The problem for Defendants is that it is not clear that prior approval must be obtained where a case is brought in federal (as opposed to state or local) court. As the EPPs point out, "[t]he plain language of the relevant statutes [identified by Defendants] indicates only that local government counsel must bring actions on behalf of the entity *in courts within their county*." Reply at 19 (emphasis in original). The EPPs also correctly note that several district courts have certified classes that include local government entities. *See, e.g.*, *In re Namenda Indirect Purchaser Antitrust Litig.*, 338 F.R.D. 527, 577 (S.D.N.Y. 2021); *In re Ranbaxy Generic Drug Application Antitrust Litig.*, 338 F.R.D. 294, 299, 309 (D. Mass. 2021); *In re Zetia Ezetimibe Antitrust Litig.*, No. MDL No. 2:18-md-2836, 2020 U.S. Dist. LEXIS 183601, at *14-15 (E.D. Va. Aug. 13, 2020). Although these cases do not contain any analysis on the specific issue before this Court, the cases suggest at least that inclusion of the local government entities did not raise any red flags for these courts.

Defendants assert still that inclusion of the local governments presents concern because local governments are unique (*e.g.*, diverse and dispersed). Although this position is not without any merit, it is not clear why the proposed class representatives could not adequately represent the local government entities in the context of this case. There does not appear to be anything to suggest that the proposed class representatives' interests would not align with those of the local government entities.

That being said, because local governments are sovereigns and may cover a wide range of constituents, the Court shall – out of an abundance of caution – implement special notice procedures for the local government entities that are members of the classes. With the assurance

of proper notice to the entities, the Court leaves it to the entities to decide for themselves whether they wish to stay in or opt out of the Damages Classes. The entities can also choose whether or not to keep track of the litigation if injunctive relief is their concern. At the hearing, the EPPs expressly stated that they were amenable to special notice procedures. Defendants also appeared amenable. Accordingly, the Court orders the parties to meet and confer to determine the best means to provide notice of class certification to the local government entities.

C. Rule 23(b)(3) Requirements – Damages Classes

For the Damages Classes, the Rule 23(a) requirements must be satisfied, plus the requirements of Rule 23(b)(3). Whether the Rule 23(b)(3) requirements have been satisfied – particularly the requirement of predominance – is at the heart of Defendants' challenge to class certification.

"'The predominance inquiry asks whether the common, aggregation-enabling issues in the case are more prevalent or important than the non-common, aggregation-defeating, individual issues.'" *Olean*, 31 F.4th at 664.

> The requirement that common questions be "more substantial" than individual ones naturally means that "predominance is a comparative standard." "The mere existence of individual issues will not suffice to defeat certification. Rather, the balance must tip such that these individual issues predominate." This ensures that only "fatal" differences among class members, which may "make use of the class-action device inefficient or unfair," will derail certification."

Namenda, 338 F.R.D. at 550.

1. Application of California Law

At the outset, Defendants contend that there is a predominance problem preventing class certification because, contrary to what the EPPs argue, California law cannot apply "across the board" – *i.e.*, to purchases/reimbursements made in all 35 repealer states. Rather, Defendants argue, the laws of all 35 repealer states must apply: in other words, which state law applies depends on where the purchases/reimbursements of the relevant prescription drugs were made. Defendants maintain that California law cannot apply across the board because doing so would be a violation of due process, California's presumption against extraterritorial application, and the

Dormant Commerce Clause.

For purposes of this opinion, the Court considers only the argument that applying California law to purchases/reimbursements outside of California would violate the state's statutory presumption against extraterritoriality.[8] There is no dispute that California has a presumption against extraterritorial application of its laws: "However far the Legislature's power may theoretically extend, [the California Supreme Court] presume[s] the Legislature did not intend a statute to be operative, with respect to occurrences outside the state, . . . unless such intention is clearly expressly or reasonably to be inferred from the language of the act or from its purpose, subject matter or history." *Sullivan v. Oracle Corp.*, 51 Cal. 4th 1191, 1270 (2011).

In *Sullivan*, the California Supreme Court addressed "questions about the applicability of California law to nonresident employees who work both here and in other states for a California-based employer [Oracle]." *Id.* at 1194. One of the issues concerned the plaintiffs' claim that Oracle, based in California, failed to compensate them according to the FLSA for overtime worked in states other than California. "This claim, despite its reference to the FLSA, arises under California [law, *i.e.*, California Business & Professions § 17200,] and not federal law." *Id.* at 1270. The California Supreme Court explained that "Plaintiffs' claim implicates the so-called presumption against extraterritorial application" because "[n]either the language of the UCL nor its legislative history provides any basis for concluding the Legislature intended the UCL to operate extraterritorially. Accordingly, the presumption against extraterritoriality applies to the UCL in full force." *Id.* (internal quotation marks omitted).

The California Supreme Court then considered "whether plaintiffs' proposed application of the UCL would cause it to operate, impermissibly, with respect to occurrences outside the state." *Id.*

> [O]nly a single instance of relevant conduct occur[ed] in California: "The decision-making process to classify Instructors as exempt from

[8] The Court does so because the extraterritoriality argument appears to the strongest of Defendants' arguments. That being said, the Court recognizes that due process and the Dormant Commerce Clause raise significant issues for the EPPs, particularly with respect to Janssen given that Janssen, unlike Gilead, is not a California-based company and thus out-of-state sales by Janssen have little connection with California.

> the requirement to be paid overtime wages under the FLSA occurred primarily from within the headquarters offices of Oracle Corporation located in Redwood Shores, California." But for an employer to adopt an erroneous classification policy is not unlawful in the abstract. What is unlawful, and what creates liability under the FLSA, is the failure to pay overtime when due. Accordingly, that Oracle's decision to classify its Instructors as exempt was made in California does not, standing alone, justify applying the UCL to the nonresident plaintiffs' FLSA claims for overtime worked in other states.

Id. at 1208.

In the instant case, the EPPs have argued for application of California's Cartwright Act and/or UCL to the 34 non-California repealer states. But the EPPs have not identified anything from the text of either statute, or the legislative history for each, that would support extraterritorial application of either statute. Thus, the presumption against extraterritoriality applies.

The Court also has doubts as to the EPPs' contention that their Cartwright Act and/or UCL claims do not involve extraterritorial application with respect to purchases/reimbursements made outside of California. The Court acknowledges that liability under the Cartwright Act – and thereby the UCL – can be based on the mere agreement to restrain trade, *i.e.*, not just the payment of supracompetitive prices. *See AT&T Mobility LLC v. AU Optronics Corp.*, 707 F.3d 1110-12 (9th Cir. 2013) (noting that, under the Cartwright Act, "the sale of price-fixed goods in California" is unlawful but so too is "the initial agreement to fix those prices – without reference to where those goods will eventually be sold"; thus, "the relevant 'occurrence or transaction' in this case includes not only the sale of price-fixed goods, but Defendants' alleged agreements and conspiracies to fix . . . prices"). And presumably, Gilead, which is based in California, made its part of the agreements to restrain trade from California. This tie to California, however, is weakened by two facts: (1) the other parties to the agreements, including Janssen, are not based in California, and (2) the agreements to restrain trade concerned purchases/reimbursements in the non-California repealer states. And as noted above, regulation of actual sales out of state implicates potential conflicts with other states' laws, and there is no indication that the California legislature intended to invite such conflict through extraterritorial application of the Cartwright Act or the UCL.

The Court, however, need not resolve this issue definitively because, even if the EPPs are

correct in arguing that extraterritorial application with respect to purchases/reimbursements outside of California were not foreclosed, that would simply mean California law *could* apply outside the state. What law would actually apply depends on a choice-of-law analysis. The Court now turns to that analysis. *Cf. Wash. Mut. Bank*, 24 Cal. 4th at 919 ("[E]ven where its own law may be constitutionally applied, California follows a three-step 'governmental interest analysis' to address conflict of laws claims and ascertain the most appropriate law applicable to the issues where there is no effective choice-of-law agreement.").

2. Choice of Law

According to Defendants, under a choice-of-law analysis, the laws of all 35 repealer states should apply, which creates a predominance problem. The EPPs disagree, contending that such an analysis would lead to application of California law. Alternatively, the EPPs contend that, even if the laws of all 35 repealer states are applicable, the variations in the laws are minimal such that individualized inquiries do not overwhelm common issues.

> When state claims are brought, federal courts apply the choice of law rules of the forum state – here, California. Under California's choice of law rules, the class action proponent bears the initial burden to show that application of California law is constitutional on the basis that California has "'significant contact or significant aggregation of contacts' to the claims of each class member." "Once the class action proponent makes this showing, the burden shifts to the other side to demonstrate 'that foreign law, rather than California law, should apply to class claims.'"
>
> California law cannot apply to the class claims if the interests of other states outweigh California's interest. To make this determination, courts use California's three-step governmental interest test. "First, the court determines whether the relevant law of each of the potentially affected jurisdictions with regard to the particular issue in question is the same or different." "Second, if there is a difference, the court examines each jurisdiction's interest in the application of its own law under the circumstances of the particular case to determine whether a true conflict exists." Finally, "if the court finds that there is a true conflict, it carefully evaluates and compares the nature and strength of the interest of each jurisdiction in the application of its own law to determine which state's interest would be more impaired if its policy were subordinated to the policy of the other state, and then ultimately applies the law of the state whose interest would be the more impaired if its law were not applied."

Stromberg, 14 F.4th at 1067-68.

a. <u>*Stromberg*</u>

The Ninth Circuit's decision in *Stromberg* is instructive as it involves a recent application of the California governmental interest test by the Ninth Circuit – although, admittedly, *Stromberg* is also distinguishable since the issue there was whether a *nationwide* class could be certified under the Cartwright Act. In contrast, here, the EPPs are not asking for certification of a nationwide class under the Cartwright Act but rather certification of (in effect) an *Illinois Brick* repealer class under the Cartwright Act.

In *Stromberg*, the plaintiffs were consumers who bought cellphones and alleged that Qualcomm maintained a monopoly by engaging in certain conduct related to chips used in cellphones. *See id.* at 1064. The district court certified a class action, holding, *inter alia*, that the plaintiffs could "seek damages on behalf of the *entire* nationwide class under the Cartwright Act." *Id.* at 1065 (emphasis added). Applying the three-step governmental interest test, the district court recognized that the "non-repealer states' antitrust laws were materially different from California's Cartwright Act on the issue of damages recovery"; however, the district court concluded, "non-repealer states have no interest in applying their laws . . . because non-repealer laws disadvantage resident consumers and are not intended to protect out-of-state businesses." *Id.*

On appeal, the Ninth Circuit disagreed. Notably, at the first step of the governmental interest, the Ninth Circuit found an error on the part of the lower court.

> There is no dispute that material differences exist between California's Cartwright Act and the antitrust laws of other states. Non-repealer states do not allow indirect purchasers to bring antitrust damages suits, while repealer states – like California – do. This difference is material because it "will spell the difference between the success and failure of a claim." *But the district court erred in its analysis at the first step because it overlooked variations in the antitrust laws of Illinois Brick-repealer states. Even among the repealer states, there are significant variations in the scope of repealer laws.* For instance, state repealer laws vary as to the type of law the repeal applies to [*e.g.*, some states limit the repeal to consumer protection statutes]; who can sue for damages [*e.g.*, Illinois allows indirect purchaser recovery but precludes class actions brought by indirect purchasers, and other states limit indirect purchaser claims to suits brought by the state attorney general]; and the amount or type of damages indirect purchasers can recover [*e.g.*, Hawaii allows indirect purchaser suits for compensatory damages only, and other states encourage or require that courts take steps necessary to avoid duplicative recovery]. Thus, the district court

> failed to "determine[] . . . the relevant law of each of the potentially affected jurisdictions," as required under California's governmental interest test.

Id. at 1068-69 (emphasis added); *see also id.* at 1074 (stating that, "[e]ven among the repealer states, the various state laws are hardly uniform").

At step two, the Ninth Circuit also rejected the lower court's conclusion that states other than California did not have an interest in applying their laws to the pending dispute. Although "California has an interest in applying its law to regulate and deter Qualcomm (a resident California corporation) from allegedly unlawful business activities in California," "other states, including non-repealer states, have an interest in how their markets are managed and how best to enforce antitrust violations and regulate commerce in *their* states." *Id.* at 1069 (emphasis added). For example:

> Non-repealer states' *Illinois Brick* laws are designed to regulate antitrust enforcement by allocating recoverable antitrust damages in a way those states think best promotes market competition. . . . [T]he relevant interests are not simply about the benefit or harm to resident consumers or liability to resident antitrust defendants; rather the relevant interests are about harm to the competitive process and in-state business activity.
>
> . . . .
>
> Allowing non-repealer states to apply their laws to class members purchasing cellphones in-state furthers those states' determinations of how to "facilitat[e] more effective enforcement of antitrust laws." The decision to bar indirect purchaser damages recovery is a policy choice regarding how a state wants antitrust laws to be enforced within its borders so competition and business can be best promoted in the state. Non-repealer laws reflect the state calculation that antitrust enforcement is best served by having indirect purchasers realize the benefit of antitrust enforcement outside of court processes. For instance, even if barred from suing for antitrust damages, indirect purchasers in non-repealer states can realize the benefit of antitrust enforcement when direct purchasers recover antitrust damages and factor that recovery into their pricing and business activity in-state, which can then be passed through to consumers in the market.
>
> Applying non-repealer laws to in-state cellphone purchases would also further state interests in reducing the risk that transactions within their borders expose businesses to excessive and "complicated" antitrust litigation with "duplicative damages" recovery. By lowering this risk, non-repealer states can attract more business in-state from entities like Qualcomm (and those who do business with Qualcomm) by creating a more favorable business

> environment. Non-repealer laws can be understood as choosing to run the risk of under-deterring antitrust violators over overcompensating plaintiffs and complicating antitrust enforcement . . . .

Id. at 1072.

The Ninth Circuit also pointed out that, even if it were to evaluate the case under tort choice of law principles (instead of antitrust choice of law principles) – as the district court had – the district court's analysis was still flawed: (1) "[t]he place of wrong, while not always controlling, 'remains a relevant consideration' in California's governmental interest test"; (2) "'[w]ith respect to regulating or affecting conduct within its borders, the place of the wrong has the predominant interest"; (3) "[t]he place of the wrong is 'the state where the last event necessary to make the actor liable occurred'"; and (4) here, "[t]he last events giving rise to liability would be the consumer's purchase of the cellphone" – which, "[i]n most instances for non-California residents, . . . would have occurred outside of California. *Id.* at 1073.

Finally, the Ninth Circuit held that, because the district court found that "only California had an interest, [it] failed to determine [at step three] which states' interests would be more impaired if their policies were subordinated to another state's law." *Id.* at 1074.

The Ninth Circuit thus remanded the case back to the district court, instructing as follows: (1) "[t]he non-repealer laws should control those purchases occurring in non-repealer states and class members with purchases in non-repealer states should be carved out of the 23(b)(3) class"; and (2) among the repealer states, the district court should "reconduct[] its choice of law analysis starting at step one." *Id.* (noting that, "[e]ven among the repealer states, the various state laws are hardly uniform").

As indicated above, *Stromberg* is not entirely dispositive of the instant case because, there, the plaintiffs sought certification of a nationwide class under the Cartwright Act; here, the EPPs are essentially asking for application of the Cartwright Act to an *Illinois Brick* repealer class. Nevertheless, *Stromberg* is instructive: certainly as to the analysis for step two of the California governmental test, but also as to step one. As noted above, at step one, the Ninth Circuit expressly stated that, "[e]ven among the repealer states, there are significant variations in the scope of repealer laws." *Id.* at 1068.

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b. Step One

At step one of the governmental interest test, this Court must "'determine[] whether the relevant law of each of the potentially affected jurisdictions with regard to the particular issue in question is the same or different.'" *Mazza*, 666 F.3d at 590. "'The fact that two or more states are involved does not itself indicate that there is a conflict of law problem.' A problem only arises if differences in state law are material, that is, *if they make a difference in [the] litigation*." *Id.* (emphasis added); *see also id.* at 591 (indicating that a trivial difference is not material and that a difference is material where, *e.g.*, it will "spell the difference between the success and failure of the claim"; also providing as an example of a material difference where there are differences in the *remedies* provided by state laws).

Defendants assert that there are material differences between California's Cartwright Act and the antitrust/consumer protection laws of the 34 other *Illinois Brick* repealer states. Appendix 1 attached to Defendants' opposition brief is a chart identifying the alleged differences.

As a preliminary matter, the Court takes note that Defendants' chart suffers from a notable problem. The following is an example. In category (1) on the chart, Defendants state: "The Cartwright Act allows private indirect-purchaser class actions. Many states do not." The second item under (1) states: "[Some states'] *[a]ntitrust* laws . . . allow only the Attorney General to bring indirect-purchaser damages suits or class actions" (emphasis added). The states identified are: Arkansas, Idaho, and Illinois. The problem for Defendants is that the EPPs have not asserted any *antirust* claims based on Arkansas, Idaho, and Illinois law. Rather, the EPPs have asserted *consumer protection* claims based on Arkansas, Idaho, and Illinois law. *Compare* FAC ¶ 592 (Count 11, violation of state consumer protection laws), *with* FAC ¶ 535 (Count 5, conspiracy to monopolize in violation of state antitrust laws).

In short, the basic problem is that Defendants identify a difference between the Cartwright Act and certain states' antitrust laws, but the EPPs are not making a claim based on those states' antitrust laws but rather based on those states' consumer protection laws. Alternatively, Defendants identify a difference between the Cartwright Act and certain states' consumer protection laws, but the EPPs are not making a claim based on those states' consumer protection

laws but rather based on those states' antitrust laws.

To be clear, this problem does not show up everywhere in Defendants' chart. However, it shows up often enough that it is notable – and throughout the chart (*i.e.*, not isolated to any category in the chart).

But putting this problem aside, Defendants have identified some differences between the Cartwright Act and some of the repealer states' laws – for instance, on Defendants' chart, with respect to the length of the statute of limitations and the damages available (*e.g.*, whether enhanced damages are available and, if so, what showing must be made). And the Court considers the differences material in that they do make a difference in this litigation. For example, for the Cartwright Act, there is a four-year limitations period, but there is a two-year period for Alabama law and a three-year period for Kansas, Mississippi, and Tennessee law. If California law were to apply across the board, the limitations period would be notably longer. *See also Mazza*, 666 F.3d at 591 (providing as an example of a material difference where there are differences in the *remedies* provided by state laws).

Thus, at step one, Defendants have met their burden of identifying some material differences – *i.e.*, between the Cartwright Act and some of the repealer states' laws.

c. Step Two

Because there are at least some material differences between the Cartwright Act and the laws of some of the other repealer states (*e.g.*, on the statute of limitations and damages), the Court moves on to step two of the governmental interest test. Here, the Ninth Circuit's *Stromberg* decision weighs in favor of Defendants – *i.e.*, in showing that, even though California may have an interest in having its Cartwright Act apply across the board because Gilead is based in California, the other repealer states still have an interest in having their own laws apply with respect to purchases/reimbursements made in their own jurisdictions and the scope of antitrust enforcement in their states. For example, a repealer state may want its shorter limitations period to apply as that reflects its policy decision as how best to balance consumer interests and business interests. The same would be true with respect to its assessment of what damages are appropriate.

d. Step Three

Based on step two, there is a true conflict, and therefore, at step three, the Court must

> evaluate[] and compare[] the nature and strength of the interest of each jurisdiction in the application of its own law to determine which state's interest would be more impaired if its policy were subordinated to the policy of the other state, and then ultimately appl[y] the law of the state whose interest would be the more impaired if its law were not applied.

Stromberg, 14 F.4th at 1068. Here, Defendants have the better argument that, as to purchases/reimbursements made in the non-California repealer states, those states' interests would be more impaired if their policies were subordinated to the policies of California. Clearly, those states have a strong interest in regulating what takes place in their own borders. Although California has an interest in having its law apply because Gilead is a California-based company, what Gilead does outside of California is of less significance.

The Court acknowledges the EPPs' citation to at least two cases where the Cartwright Act was applied across the board. *See* EPP Mot. at 17. But both of those cases were decided before *Stromberg*, and the analysis in those cases is not extensive. *See In re Optical Disk Drive Antitrust Litig.*, No. 3:10-MD-2143 RS, 2016 WL 467444, at *14 (N.D. Cal. Feb. 8, 2016) (taking note of defendants' contention that "California law should not even be applied to repealer states [because] there still exist numerous differences between the California antitrust and unfair competition laws and those in many of the other 24 jurisdictions[;] [t]he parties were specifically given the opportunity to submit additional briefing," but, "[a]part from the *Illinois Brick* issue, . . . the potential differences identified between California and some of the other jurisdictions do not appear to stand as true conflicts, or as ones that should not yield to California's interests"); *In re Korean Ramen Antitrust Litig.*, No. 13-cv-04115-WHO, 2017 WL 235052, at *22-23 (N.D. Cal. Jan. 19, 2017) (stating that "Defendants have not identified any conflicts to applying the Cartwright Act to the 24 *Illinois Brick* repealer jurisdictions"). Accordingly, the Court declines to follow those decision.

The Court concludes that the governmental interest test does not support California law being applied across the board; rather, the Court must apply the laws of each of the repealer states

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with respect to the purchases/reimbursements made in that state.

e. Variance Among Laws of the Repealer States

That the laws of the 35 repealer states apply, however, is not the end of the inquiry – *i.e.*, it does not mean that Rule 23(b)(3)'s predominance requirement cannot be met. As the EPPs argue, even though there may be some differences in the laws of the repealer states (*e.g.*, on the statute of limitations and damages), the question is how much variance is there. *See Namenda*, 338 F.R.D. at 571 ("[A] plaintiff must demonstrate that 'any variations in relevant state laws do not predominate over the similarities.'"); *cf. Stromberg*, 14 F.4th at 1067 ("'[V]ariances in state law [can] overwhelm common issues and preclude predominance for a single nationwide class.'"). In *Namenda*, the New York district court noted that "[m]any indirect-purchaser classes have been certified even though they were brought under the laws of different states," which "follows the Supreme Court's dicta that '[p]redominance is a test readily met in certain cases alleging . . . violations of the antitrust laws.'" *Namenda*, 338 F.R.D. at 571. Defendants, of course, disagree – citing once again their chart in Appendix 1 attached to the opposition brief.

The Court addresses variance with respect to each legal claim – antitrust and consumer protection – separately. *See Provine v. Office Depot, Inc.*, No. C 11-00903 SI, 2012 U.S. Dist. LEXIS 93881, at *29 (N.D. Cal. July 6, 2012) ("Plaintiff must establish that common questions of law or fact predominate for each claim in which he seeks to certify a class."). *Namenda* is an instructive case on this issue of variance. In *Namenda*, the plaintiff asserted (1) antitrust violations (monopolization and restraint of trade) arising under the laws of 25 jurisdictions and (2) consumer protection violations under the laws of 14 jurisdictions. *See Namenda*, 338 F.R.D. at 571. The court concluded that there was no significant variation such that the Rule 23(b)(3) predominance requirement was met.

i. Antitrust

On the antitrust claims, the *Namenda* court noted first that "[m]any indirect-purchaser classes have been certified even though they were brought under the laws of different states," which "follow[ed] the Supreme Court's dicta that '[p]redominance is a test readily met in certain cases alleging . . . violations of the antitrust laws.'" *Id.*

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The court then went on to conclude that there was no significant variance among the antitrust laws of the 25 jurisdictions because:

- Almost all of the state statutes had language similar to that in §§ 1 and 2 of the Sherman Act (*i.e.*, restraint of trade and monopolization). *See id.* at 572.
- "[E]ven the states that have statutes that do not closely track the language of the Sherman Act have effectively harmonized their antitrust statutes with that of the federal law such that the elements needed to sustain a monopolization or restraint-of-trade claim – at the most basic level – are effectively the same under the state and federal laws." *Id.*
- There was no other "indication that any state's antitrust laws require proof of elements different from those that must be proved under the Sherman Act with respect to monopolization or restraint-of-trade claims." *Id.*

The court acknowledged that, in the absence of any "substantive discrepancy between the various state antitrust laws," the defendants invoked "procedural discrepancies." *Id.* For example, the defendants noted that there was variance among the states with respect to the applicable statutes of limitations. However, the court did not find this variance enough to create a predominance problem. "Variations in limitations periods are irrelevant to whether there exist common questions of law or fact that go to the heart of Defendants' potential liability as to the claims alleged." *Id.*; *see also id.* at 574 (stating that defendants failed to "explain[] why any such differences [on limitations periods] would make adjudication of [plaintiff's] claims overly burdensome, or why these differences would predominate the core antitrust questions that underpin [plaintiff's] allegations").

The instant case is similar to *Namenda*. Like the defendants in *Namenda*, Defendants here have not pointed to any "substantive discrepancies" between the antitrust laws of the 35 repealer states. And in Appendix A attached to their motion, the EPPs have cited authority to support their position that state antitrust laws are guided by federal antitrust law such that there is "harmonization" among the various state antitrust laws.

In addition, like the defendants in *Namenda*, Defendants have primarily relied instead on

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"procedural discrepancies" such as differences in limitations periods or in damages available (*e.g.*, whether enhanced damages are available and, if so, what showing must be made). But as in *Namenda*, these variances are not that significant. For the statute of limitations, even if the Cartwright Act has a limitations period of four years and other states' antitrust claims are subject to a shorter limitations period (two or three years), that does not create much variation and does not detract from the common issues on liability, whether the theory is based on, *e.g.*, the Teva patent settlements or the NGRs. The differences in limitations periods can be managed at trial via jury instructions and verdict form. The same is true with respect to damages – *i.e.*, even if the Cartwright Act provides for treble damages automatically while other states' antitrust laws limit damages to actual damage or only allow for enhanced damages based on a higher showing (such as flagrant or willful conduct), that is a relatively minor variation and does not overwhelm the common issues on liability. For example, Defendants have not shown that, for enhanced damages, there is any practical difference between the various states' laws: while some states require, *e.g.*, flagrant, intentional, malicious, or willful conduct as a condition to enhanced damages, Defendants have not shown that there are meaningful differences among those states in the required showing. Thus, again, this is a variable that can feasibly be managed at trial.

ii. Consumer Protection

The *Namenda* court also found no significant variance problem to the extent the plaintiffs were bringing consumer protection claims based on the laws of 14 jurisdictions. "Like the antitrust statutes, many of these statutes are worded identically in that they prohibit 'unfair methods of competition,'" and other statutes used "extremely similar [language], prohibiting 'unconscionable' or otherwise 'deceptive' or 'fraudulent' practices." *Id.* The court recognized the defense argument that "'unfair' is not necessarily the same as 'unconscionable' or 'deceptive'" but it concluded that the defendants did

> no more than simply point out the existence of . . . slight discrepancies. They do not identify how [plaintiff's] allegations may "fail to satisfy the required elements under the laws of these jurisdictions," or whether they may be cognizable under certain statutes but "not cognizable claims under the consumer protection laws of" others. Although they cite to state court cases that purportedly demonstrate different "tests" as to what constitutes an

> unfair practice, Defendants fail to show – in practice – how the statutes would be applied differently in *antitrust cases* like this one. There is no indication whatever that the serious antitrust allegations that SBA advances in this case – if proven – would not be a violation of each of these states' consumer-protection statutes.

Id. (emphasis in original).

The court added that,

> [u]ltimately, any substantive variations that may arise from the discrepancies within these consumer-protection statutes are eliminated by the fact that nearly all of the states in question also have statutes that harmonize state provisions with that of the Federal Trade Commission Act. These harmonization provisions re critical because "practices that violate the Sherman Act and other antitrust laws" satisfy the standard of "unfairness" under the FTC Act. This means that "state laws with equivalent 'unfairness' language and an FTC harmonization provision can safely be assumed to have similarly broad scope." More precisely, any conduct that would qualify as "unfair" under the FTC Act – which violations of the antitrust laws certainly would – would also violate the state provisions at issue. This serves to make it such that any anticompetitive conduct – if proven – would constitute an unfair trade practice such that "proof of anticompetitive conduct [will] establish[ ] a violation of each state's laws."

Id.

Although *Namenda* provides some guidance for the consumer protection claims here, it is less instructive compared to the analysis for the antitrust claims. That is because, here, Defendants have claimed more than slight discrepancies among the consumer protection laws at issue – *e.g.*, they have asserted that some states' consumer protection laws bar class actions or do not cover antitrust/anticompetitive conduct. Notably, at the hearing, the EPPs essentially acknowledged that (1) many, if not all, states' consumer protection laws covered deceptive conduct and that (2) the EPPs had pled a fraudulent concealment theory in the operative complaint, *see, e.g.*, FAC ¶ 585 (Count 11, violation of state consumer protection laws), *but* that (3) for class certification purposes, their state consumer protection claims were based on antitrust/anticompetitive conduct only. In short, at this juncture, the EPPs are not pursuing a deception-based theory. This simplifies the issue.

Furthermore, the Court notes that some of Defendants' criticisms are not that significant – at least from a "big picture" perspective – because, even if there is a problem with a given state

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law consumer protection claim, the EPPs have *also* asserted a claim under that state's antitrust law.[9] There are only a few instances in which Defendants are challenging a state's consumer protection claim *and* there is no antitrust claim under that state's law to serve as an alternative or backup. In this order, the Court focuses on this specific situation only because certification with respect to a given state would be problematic only if no antitrust claim is pled *and* no consumer protection claim is viable either.

- **Arkansas.** Arkansas's consumer protection statute prohibits "[d]eceptive and unconscionable trade practices." Ark. Code. Ann. § 4-88-107(a). It gives examples of deceptive and unconscionable trade practices but expressly notes that the examples "are in addition to and do not limit the types of unfair trade practices actionable at common law or under other statutes of this state." *Id.* § 4-88-107(b). In *Lidoderm*, Judge Orrick of this District noted that three judges in the District have "held that price fixing allegations are sufficient to state 'unconscionable' conduct under the ADTPA," but that three other judges "have found that even in light of the broad definition of unconscionability adopted by the Arkansas Supreme Court, in absence of authority from Arkansas courts that the ADTPA extends to price fixing claims, those claims should be dismissed." *Lidoderm*, 103 F. Supp. 3d at 1166. Judge Orrick ultimately sided with the latter group based on the "split in federal authority and the absence of authority from Arkansas." *Id.* at 1167. The Court agrees with Judge Orrick. Furthermore, the fact that "[t]he ADTPA is not patterned directly on the FTC Act and does not contain a provision harmonizing its interpretation with that of the FTC Act," *In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 350 F. Supp. 2d 160, 178 (D. Me. 2004), is instructive. Finally, the

[9] For example, in Category 4 on Defendants' Appendix 1, Defendants contend that many state consumer protection laws "proscribe enumerated conduct, *excluding* antitrust conduct." Opp'n, App. 1, at 2 (emphasis added). However, the EPPs are not asserting consumer protection claims under Alabama, Maryland, Oregon, and South Dakota law. *See* FAC ¶ 583 *et seq.* (Count 11, violation of state consumer protection laws). As for Michigan, Nevada, Rhode Island, Tennessee, and West Virginia, even if Defendants are right about these states' consumer protection laws, the EPPs have also brought claims under these states' antitrust laws.

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Court takes into account that the Arkansas consumer protection statute contains the following provision: "A person who suffers an actual financial loss as a result of his or reliance on the use of a practice declared unlawful by this chapter may bring an action to recover his or her actual financial loss proximately caused," but "[a] private class action under this subsection is prohibited unless the claim is being asserted for a violation of Arkansas Constitution, Amendment 89." Ark. Code Ann. § 4-88-113(f)(1)(A)-(B). The Court concludes that this provision should be given effect in federal court. In a prior order, it has given effect to a similar provision based on Justice Stevens's concurrence in *Shady Grove Orthopedic Associates, P.A. v. Allstate Insurance Co.*, 559 U.S. 393 (2010) – concluding that Rule 23 does not govern if the state law prohibiting the class action is so intertwined with a state right or remedy that it functions to define the scope of the state-created right. *See Staley*, 446 F. Supp. 3d at 626 (holding that "the Illinois prohibition on class actions is deeply intertwined with the rights under the *Illinois Brick* repealer"); *see also In re MyFord Touch Consumer Litig.*, No. 13-cv-03072-EMC, 2016 U.S. Dist. LEXIS 179487, at *77-78 (N.D. Cal. Sep. 14, 2016).

- **Idaho.** The purpose of the Idaho consumer protection statute "is to protect . . . against unfair methods of competition and unfair or deceptive acts and practices in the conduct of trade or commerce." Idaho Code § 48-601. The statute notes that "[i]t is the intention of the legislature that this chapter be remedial and be so construed." *Id.* It further notes that "[i]t is the intent of the legislature that in construing this act due consideration and great weight shall be given to the interpretation of the federal trade commission and the federal courts relating to section 5(a)(1) of the federal trade commission act (15 U.S.C. 45(a)(1)) . . . ." *Id.* § 48-604. Notwithstanding such, the Idaho Supreme Court has indicated that there are differences between the FTCA and the Idaho consumer protection statute that cannot be "ignore[d]." *State v. Daicel Chem. Indus., Ltd.*, 14 Idaho 102, 107 (2005). While the U.S. Supreme Court has held that price-fixing violates the

FTCA, the FTCA does *not* "define what constitutes unfair methods of competition"; in contrast, the Idaho statute "lists nineteen types of conduct that constitute either an unfair method of competition or an unfair or deceptive act or practice [including unconscionable acts or practices]. There is nothing in the wording of Idaho Code § 48-603 indicating that the list of conduct is merely illustrative. Price-fixing is not listed in § 48-603 as conduct that constitutes either an unfair method of competition or an unfair or deceptive act or practice. The legislative intent that we give due consideration and great weight to the interpretation given the FTCA by federal courts only applies when we are construing a provision of the federal law that is similar to that in our Act." *Id.* at 107-08; *see also id.* at 109 (also holding that the alleged conduct did not meet the definition of unconscionable acts or practices). In light of the Idaho Supreme Court's holding in *Daicel*, the EPPs have no viable consumer protection claim under Idaho law. *See also In re Dynamic Random Access Memory Antitrust Litig.*, 516 F. Supp. 2d 1072, 1110 (N.D. Cal. 2007) (finding *Daicel* "directly on point, . . . compel[ing] the conclusion here that plaintiffs' claim pursuant to the CPA, based on similar allegations of price-fixing and horizontal price restraints, must fail").

- **Illinois.** The Illinois Consumer Fraud and Deceptive Business Practices Act prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices." 815 Ill. Comp. Stat. Ann. § 505/2. It expressly states that, "[i]n construing this section consideration shall be given to the interpretations of the Federal Trade Commission and the federal courts relating to Section 5 (a) of the Federal Trade Commission Act." *Id.* Nevertheless, the Illinois Supreme Court has held that the Illinois Consumer Fraud Act is not intended to be "an additional antitrust enforcement mechanism." *Laughlin v. Evanston Hosp.*, 133 Ill. 2d 374, 390 (1990). In light of *Laughlin*, "this Court joins the majority of other courts in concluding that the EPPs do not have standing to maintain what is in essence an antitrust claim by another name under the Illinois Consumer Fraud and Deceptive

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Business Practices Act." *In re Loestrin 24 Fe Antitrust Litig.*, 410 F. Supp. 3d 352, 372-73 (D.R.I. 2019). Notably, the Court previously dismissed the Illinois *antitrust* claim because, even though Illinois is a repealer state, the state statute has a provision that bars class actions by indirect purchasers. *See Staley*, 446 F. Supp. 3d at 624-26).

- **Missouri.** Missouri's consumer protection statute deems an unlawful practice "[t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce . . . in or from the state of Missouri." Mo. Rev. Stat. § 407.020. Regulations interpreting the statute provide that "[a]n unfair practice is any practice which – (A) Either – 1. Offends any public policy as it has been established by the Constitution, statutes or common law of this state, or by the Federal Trade Commission, or its interpretive decisions; or 2. Is unethical, oppressive or unscrupulous; and (B) Presents a risk of, or causes, substantial injury to consumers." 15 C.S.R. § 60-8.020(1); *see also id.* § 60-8.020(2) (providing that "[p]roof of deception, fraud, or misrepresentation is not required to prove unfair practices as used in section 407.020.1"); *Schuchmann v. Air Servs. Heating & Air Conditioning, Inc.*, 199 S.W.3d 228, 234 (Mo. Ct. App. 2006) ("looking at the Federal Trade Commission's ('FTC') interpretation of 15 U.S.C. § 45(a) (declaring 'unfair or deceptive acts or practices' affecting commerce are unlawful)"). In light of the regulations, the Court concludes that there is a viable consumer protection claim under Missouri law based on the anticompetitive conduct alleged herein. *See In re Pool Prods. Distrib. Mkt. Antitrust Litig.*, 946 F. Supp. 2d 554, 571-72 (E.D. La. 2013) (noting that "[a]ntitrust violations are deemed unfair methods of competition under the FTC Act" and therefore "IPPs['] allegations of antitrust violations are . . . sufficient to make out a claim of unfair practices under the MMPA"). The Court acknowledges the authority cited by Defendants, holding that

"[t]he plaintiffs cannot avoid [Missouri's] antitrust prohibition on indirect purchaser suits by making the same claim under Missouri's consumer protection statute." *New Motor Vehicles*, 350 F. Supp. 2d at 192. But the Court previously rejected this argument in a prior order. *See Staley*, 446 F. Supp. 3d at 633 (rejecting Defendants' argument that "Plaintiffs cannot try to 'end run' the *Illinois Brick* rule by recasting the antitrust claims as consumer protection claims").

- **Montana.** Montana law has the following provision in its Consumer Protection Act: "Except as provided in subsection (1)(b), a consumer who suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment by another person of a method, act, or practice declared unlawful by 30-14-103 may bring an individual action but not a class action under the rules of civil procedure in the district court of the county in which the seller, lessor, or service provider resides or has its principal place of business or is doing business to recover money damages in the amount of any ascertainable loss of money or property or $500, whichever is greater. . . . ." Mont. Code Ann. § 30-14-133(1)(a). Based on this provision, Defendants argue that the EPPs do not have a valid consumer protection claim based on Montana law because such law bars class actions. The Court agrees with Defendants. As the Court has noted in previous decision, Rule 23 does not govern if the state law prohibiting the class action is so intertwined with a state right or remedy that it functions to define the scope of the state-created right. *See, e.g.*, *MyFord Touch*, 2016 U.S. Dist. LEXIS 179487, at *78-79 (concluding that "Colorado's limitation on class actions is intertwined with the state right" because the limitation "appears in the substantive section of the code, rather than in court rules" and "is part of the same paragraph which would otherwise make it possible for Plaintiffs to sue for damages"; also noting that "the limitation applies only to Colorado's Consumer Protection Act, suggesting it reflects a substantive policy judgment as to the area of the law by the legislature, not a rule of general procedure"); *Staley*, 446 F. Supp. 3d at 626 (concluding that

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"the Illinois prohibition on class actions is deeply intertwined with the rights under the *Illinois Brick* repealer").

For the foregoing reasons, the Court finds Defendants' arguments on the state consumer protection laws of Arkansas, Idaho, Illinois, and Montana persuasive. But the problem for Defendants is that, even if this creates some "variance" among state laws on consumer protection, there is a simple solution. The consumer protection claims based on these state laws are dismissed, and the EPPs cannot seek class certification based on these states because (1) the consumer protection claims are not viable and (2) the EPPs have not asserted any alternative antitrust claims. *Cf. In re Solodyn Antitrust Litig.*, No. 14-md-02503, 2017 U.S. Dist. LEXIS 170676, at *68-69 (D. Mass. Oct. 16, 2017) (noting that some of defendants' arguments went "beyond mere variations in the state statutes that could be remedied by juror forms" – *e.g.*, defendants asserted that "Montana's and Utah's consumer protection statutes prohibit class actions"; agreeing with defendants on Montana law and thus excluding Montana's consumer protection statute from the putative class's claims).

iii. Summary

For the foregoing reasons, the Court does not find significant variation among the laws of the repealer states at issue on the antitrust claims sufficient to defeat predominance, even taking into account differences based on statutes of limitations and damages. The Court also does not find significant variation among the laws of the repealer states at issue on the consumer protection claims, once the claims based on the laws of Arkansas, Idaho, Illinois, and Montana are dismissed.

3. Antitrust Injury or Impact

Defendants argue that, even if the choice-of-law issue does not present a predominance problem, the EPPs still cannot meet Rule 23(b)(3)'s predominance requirement because they cannot litigate "antitrust injury" without there being individualized inquiries. In other words, according to Defendants, there are a number of TPPs who were *not* injured as a result of the alleged antitrust violations (only TPPs make up the Damages Classes), and to determine who those TPPs are requires individualized inquiries which will swamp the common questions that do exist.

The Supreme Court has stated that "[c]onsidering whether 'questions of law or fact

common to class members predominate' begins . . . with the elements of the underlying cause of action." *Erica P. John Fund, Inc. v. Halliburton Co.*, 563 U.S. 804, 809 (2011). As a general matter, "[t]he elements of a claim for [an] antitrust action are (i) the existence of an antitrust violation; (ii) 'antitrust injury' or 'impact' flowing from that violation . . . ' and (iii) measurable damages." *Olean*, 31 F.4th at 665-66.

Because the first element "is primarily a determination that focuses on the defendants' conduct – *i.e.*, whether the conduct alleged would actually violate the antitrust laws – common evidence generally predominates over individualized evidence with regard to this element." *Namenda*, 338 F.R.D. at 551. But the second element – often called antitrust injury, antitrust impact, or impact and causation – focuses on how the plaintiffs were harmed. *See id.* "When individualized questions relate to the injury status of class members, Rule 23(b)(3) requires that the court determine whether individualized inquiries about such matters would predominate over common questions." *Olean*, 31 F.4th at 668.

As a preliminary matter, the Court notes that there is some question as to whether the injury status of specific class members is of any real significance in the instant case – specifically, for purposes of predominance – if the EPPs are correct that they can prove aggregate damages (that is, damages on a classwide basis). In other words, so long as the EPPs can prove aggregate damages, then which specific TPPs have actually been injured and/or to what extent is simply a matter of damages allocation, a matter that can be handled in a bifurcated proceeding.[10] *See Solodyn*, 2017 U.S. Dist. LEXIS 170676, at *40-41 ("The use of averages to develop the aggregate amount of damages does not suggest Plaintiffs will be unable to ensure recovery is only for injured parties. 'Apportioning damages ought wait until liability is decided upon the merits . . . .'"); *cf. In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 233 (E.D. Pa. 2012) ("GSK's other challenges to Rausser's methodology 'are concerns that relate primarily to the allocation of damages among individual class members, not to the computation of aggregate damages on a

[10] As reflected in their proposed trial plan, the EPPs have suggested a two-phase trial: Phase I would address liability, aggregate damages, and injunctive relief; Phase II would involve allocation of the aggregate damages. *See* Huttinger Decl., Ex. 6 (EPPs' proposed trial plan).

class-wide basis. Assuming the jury renders an aggregate judgment, allocation will become an intra-class matter accomplished pursuant to a court-approved plan of allocation, and such individual damages allocation issues are insufficient to defeat class certification.'”).

But assuming that Defendants are correct that injury status does matter, the Court bears in mind the following: (1) if there is only a de minimis number of uninjured TPPs, that may not be enough to prevent certification, and (2) even if there is *more* than a de minimis number of uninjured TPPs, that does not automatically preclude certification. Regarding the latter, the Ninth Circuit has expressly rejected the

> argument that Rule 23 does not permit the certification of a class that potentially includes more than a de minimis number of uninjured class members [because] [t]his position is inconsistent with Rule 23(b)(3), which requires only that the district court determine after rigorous analysis whether the common question predominates over any individual questions, including individualized questions about injury or entitlement to damages.[11]

Olean, 31 F. 4th at 669.

a. Antitrust Injury Theories

In order to consider Defendants' contention that there is a sizeable number of uninjured TPPs, the Court must first take into account the EPPs' theories of antitrust injury. The EPPs have an expert, Dr. Frank, who has submitted two reports (an opening reply and a reply report) that address antitrust injury.

In his reports, Dr. Frank provides general background based on, *e.g.*, research from academia, the government, and the pharmaceutical industry. That background includes the following:

- When a generic drug launches, it is priced at a discount compared to the brand

[11] Judge Lee dissented in *Olean*, asserting, *e.g.*, that "Rule 23 allows a *de minimis* number of uninjured members but no more." *Olean*, 31 F.4th at 692 (Lee, J.). According to Judge Lee, other circuit courts have "endorsed a *de minimis* rule. The D.C. Circuit, for example, suggested that '5% to 6% constitutes the outer limits of a *de minimis* number,'" and "the First Circuit suggested that 'around 10%' of uninjured class members marks the *de minimis* border." *Id.* The Ninth Circuit majority disagreed. *See id.* at 669 n.13 (concluding that those circuits had not "adopted a per se rule[;] [r]ather, based on the particular facts of the cases before them, our sister circuits held that Rule 23(b)(3)'s predominance requirement is not satisfied when the need to identify uninjured class members 'will predominate and render an adjudication unmanageable'").

drug. The generic price discount is usually larger where, pre-generic entry, the brand drug has significant sales. In addition, the generic price discount usually increases over time as more generics enter the market (*i.e.*, there is not just one generic manufacturer selling a generic drug in lieu of the brand but rather multiple generic manufacturers which results in further depression of the generic price). *See* Frank Rpt. ¶¶ 73-80.

- "When generic drugs launch, they rapidly capture the great majority of market share from the reference brand drug." Frank Rpt. ¶ 91. "[T]his rapid generic conversion is driven partly by the generic price discounts but also by institutional factors such as state automatic substitution laws and managed care policies including tiered formularies (which are designed to take advantage of the low prices for generics)." Frank Rpt. ¶ 94.
- In response to the entry of a generic, the brand manufacturer usually lowers the price of the brand drug. *See* Frank Rpt. ¶ 104.

Dr. Frank then goes on to describe three types of antitrust injury in the instant case: (1) brand-generic injury; (2) generic-generic injury; and (3) brand-brand injury. Notably, "[i]f a TPP paid an overcharge on a *single* transaction with respect to any *one* of these types of injury, then it experienced antitrust injury." Frank Rpt. ¶ 128 (emphasis added). In other words, if there is just one overcharge with respect to just one member of a TPP (*i.e.*, an individual consumer), then the TPP is injured.

- **Brand-generic injury.** "Brand-generic overcharges occur when patients who would have otherwise consumed [a] generic [drug] are instead forced to consume [the] branded [drug] because generic entry was delayed." *Namenda*, 338 F.R.D. at 564; *see also* Frank Rpt. ¶ 128(a) ("Brand-generic injury is an overcharge on purchases of the brand drug that would have been purchases of the lower-priced generic equivalent in the but-for world.") (emphasis omitted). Dr. Frank asserts that most TPPs have suffered this kind of injury. He notes, for instance, that, for Atripla and Truvada, the *actual* world data shows that, "17 months after the

Truvada and Atripla generic launches, generics have captured 96.9% of the Truvada molecule pills and 97.5% of the Atripla molecule pills."[12] Frank Reply Rpt. ¶ 43. With such high generic conversion rates in the *actual* world, it can reasonably be inferred that there would be similar generic conversion rates in the but-for world.[13] For Complera, there is no actual world data because no generic version of Complera is available yet. Thus, Dr. Frank had to estimate what the generic conversion rate for Complera would be using a "yardstick" drug (*i.e.*, what he deemed to be a comparable drug). That yardstick drug (Trizivir) had a generic conversion rate of about 80% approximately 18 months after generic entry and eventually reached a conversion level of about 90%. *See* Frank Rpt. ¶ 99 & Fig. 6 (chart reflecting generic conversion rate for comparable drug Trizivir). Dr. Frank took into account that there may be some consumers who still purchase brand drugs after the entry of generics – *i.e.*, are brand loyal – because, *e.g.*, they are reluctant to change from what works or because the cost of the brand drug is tempered or even entirely eliminated as a result of cost-sharing assistance programs or patient assistance programs. However, "[g]iven conversion rates of [*e.g.*] 97% to 98%, to the extent this phenomenon is occurring, it is not effectively reducing the conversion of the market to the generics." Frank Reply Rpt. ¶ 53. Moreover, while there may be *consumer* brand loyalty, the question here is whether there is *TPP* brand loyalty (as only TPPs are in the Damages Classes). Defendants' expert, Dr. James Hughes, suggests that there is effectively TPP brand loyalty to the extent that a number of TPPs are small and have only a few enrollees who purchase the drugs

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[12] A "molecule" is the combination of a brand drug and its generic equivalents. *See* Frank Rpt. at 45 n. 210; *see also* Frank Rpt. ¶ 74. The generic launch of Truvada, as well as the generic launch of Atripla took place in October 2020. *See* Frank Rpt. ¶ 50 (Truvada); Frank Rpt. ¶ 59 (Atripla). Multiple generics entered the market with respect to Truvada, as well as Atripla, starting in March 2021. *See* Frank Rpt. ¶ 51 (Truvada); Frank Rpt. ¶ 60 (Atripla).

[13] In fact, Dr. Frank indicates that actual world data understates what the generic conversion rate would be in the but-for world because, *e.g.*, in the actual world, there was only one generic for the first 6 months after generic entry, but, in the but-for world, there would have been multiple generics starting in the first month. *See* Frank Reply Rpt. ¶ 71(a).

at issue – *i.e.*, if a TPP has only one enrollee who purchases the drugs and that enrollee is brand loyal, then the TPP is essentially brand loyal too. *See* Frank Reply Rpt. ¶ 83. But "[a] TPP would avoid brand-generic injury only if it has *exclusively* 'brand-loyal' members." Frank Reply Rpt. ¶ 87 (emphasis added). In other words, if just one TPP member (*i.e.*, enrollee) bought a generic drug one time, that would be injury to the TPP. *See Solodyn*, 2017 U.S. Dist. LEXIS 170676, at *62 (noting that "an insurer with brand-loyal members is only uninjured here if everyone of its members would have been brand-loyal for all Solodyn purchases in each 'but-for' scenario"); *Namenda*, 338 F.R.D. at 562 (stating that "any one TPP would have suffered an antitrust injury as long as it provided reimbursement for just one overcharged transaction of Namenda or a generic alternative to someone who was not brand loyal").

- **Generic-generic injury.** "Generic-generic injury is an overcharge on purchases of the generic drug that would have been purchases of the lower-priced generic drug in the but-for world." Frank Rept. ¶ 128(b) (emphasis omitted). This injury relates to only the Truvada and Atripla Classes since there is no generic version of Complera available yet. "Both Truvada and Atripla had generics launch in October 2020, and every purchase of a generic from Teva in the actual world would also have been a purchase of a generic in the but-for world. In each one of those generic purchases, the Class members paid an overcharge. The primary reason is that the generic price would have been lower in the but-for world than it was in the actual world. This is the case for two reasons: First, generic prices typically decline over time, so a but-for generic that that would have launched would ordinarily be priced lower than the actual generic that launched later. Second, generic prices are set based on the price of the brand drug when the first generic competitor launched. Since brand prices almost always increase over time until an initial generic launch, a generic that first launched earlier will have a lower price than one that first launched later." Frank Rpt. ¶ 134.

- **Brand-brand injury.** "Brand-brand injury is an overcharge on purchases of the brand drug that would have been purchases of the lower-priced brand drug in the but-for world." Frank Rpt. ¶ 128(c) (emphasis omitted). "A small percentage of brand purchases in the actual world would also have been brand purchases in the but-for world. In those brand purchases, Class members would still have paid an overcharge. The primary reason is that the brand price would have been lower in the but-for world than it was in the actual world. This is the case because the prices of Truvada and Atripla decreased after generic entry in the actual world, indicating that they would have done the same in the but-for world. The effect of this is that the brand prices of Truvada and Atripla in the but-for world would have been lower than they were in the actual world. In the case of Complera, there is no actual generic entry to provide evidence of what would have happened to Complera brand prices after generic entry in the but-for world; however, other evidence indicates that the Complera brand price in the but-for world would indeed have decreased after generic entry. First, the yardstick for Complera – Trizivir – experienced a decrease in brand price after generic entry. In addition, other cART drugs exhibited the same pattern."[14] Frank Rpt. ¶ 135.

Defendants acknowledge the different antitrust injury theories but argue that, for each theory, individualized inquiries are necessary to determine who is not injured. As discussed below, none of Defendants' arguments is persuasive, especially since the EPPs simply have to establish that they have evidence "capable of showing that [the class members] suffered antitrust impact on a class-wide basis." *Olean*, 31 F.4th at 681.

i. Evidence of Antitrust Injury

Defendants argue first that the EPPs' economic evidence *assumes*, rather than proves, antitrust injury: "For instance, depending on the TPP, some, all or none of its members switched

[14] *See also* Frank Reply Rpt. ¶¶ 33, 36 (discussing factors that point to brand-brand injury – *e.g.*, "the continual increase in actual-world prices and the increase in brand consumer cost sharing for brand drugs that occurs after generic entry").

or would have switched to an AB-rated generic alternative." Opp'n at 19. But Defendants ignore two points: (1) for a TPP to be injured, just *one* member of the TPP (*i.e.*, individual enrollee) needs to have swapped a generic for a brand drug *one* time; and (2) the EPPs have presented evidence that there is a high generic conversion rate – for Truvada and Atripla, over 95%. Although Trizivir (the yardstick drug for Complera) had a "less rapid generic conversion" compared to some other cART drugs, it eventually reached a generic conversion rate of 92%. Frank Rpt. ¶ 97.

Defendants also argue that, "depending on the TPP, product, location, and consumer, the portion of the retail price the TPP actually paid and would have paid in a 'but-for' world varies from 0% to 100%." Opp'n at 19. But Dr. Frank has explained in his report[15] that, even though the payments made by TPPs are not exactly equal to the retail price because, *e.g.*, "they are partly offset by consumer cost-sharing," it is unlikely that, in the but-for world, an offset from a co-pay for a generic would "eliminate the TPP's overcharge." Frank Rpt. ¶ 132(b) (noting, *e.g.*, that, "because of the high prices of these drugs, consumer cost sharing is a small fraction of the drug retail price, so offsets from cost-sharing would not eliminate the overcharge in any material number of transactions"). Importantly, Defendants' argument relates more to the issue of damages allocation, not antitrust injury. There is evidence of class-based injury from the challenged conduct – evidence of antitrust injury. Issues as to Phase II damages allocation do not defeat predominance. *See generally* Huttinger Decl., Ex. 6 (EPP's Prop. Trial Plan ¶ II.B) ("The allocation of damages in Phase II will not involve any issues related to Defendants or their liability, but instead concerns only issues that are internal to the Class. Allocation will be decided by the Court, not the jury – the jury will be dismissed after rendering a verdict on liability and aggregate damages in Phase I.").

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[15] "The determination whether expert evidence is capable of resolving a class-wide question in one stroke may include '[w]eighing conflicting expert testimony' and '[r]esolving expert disputes,' where necessary to ensure that Rule 23(b)(3)'s requirements are met and the 'common, aggregation-enabling" issue predominates over individual issues." *Olean*, 31 F.4th at 666.

ii. Brand-Generic Injury

The most significant antitrust injury claimed by the EPPs is brand-generic injury. Defendants' main challenge to brand-generic injury relates to brand loyalty. According to Defendants, there are individualized inquiries with respect to brand-generic injury because some TPP members (*i.e.*, individual consumers) would have continued to purchase brand drugs even after generic launch. *Cf., e.g., Lidoderm*, 2017 U.S. Dist. LEXIS 24097, at *90-91 (noting that both parties' experts removed brand-loyal consumers from the damages calculations).

In assessing this argument, the Court bears in mind the following:

(1) There may well be legitimate reasons for a TPP member (*i.e.*, individual consumer) to be brand loyal – *e.g.*, because of "manufacturer financial assistance for persons living with HIV, the tendency of insurance companies not to restrict access to brand HIV therapies, and strong preferences to keep patients on life-saving HIV medication that is working for them." Opp'n at 22. However, the generic conversion rates for Truvada and Atripla in the actual world (97-98%) suggest that the number of brand-loyal consumers is relatively small.

(2) Brand loyalty by a TPP *member* (*i.e.*, individual consumer) does not thereby make the *TPP* brand loyal. For the TPP to be brand loyal, *all* of its members would have to be brand loyal. Defendants' expert, Dr. Hughes, essentially admits this. *See, e.g.*, Hughes Rpt. ¶ 84. Or to state the matter somewhat differently, a TPP is injured so long as *one* of its members would have, on *one* occasion, bought generic in lieu of brand.

(3) Even if there were some brand-loyal TPPs, Dr. Frank has explained why there is still brand-brand injury.

According to Defendants, the percentage of brand-loyal consumers for the relevant drugs is high. For example, "22 percent of Truvada patients, and 34 percent of Atripla patients[] continued purchasing the at-issue brand drug during the period October 2020 through August 2021, i.e., even after generic equivalents became available." Hughes Rpt. ¶ 83. In his reply report, however, Dr. Frank explains why this statement from Dr. Hughes is not accurate.

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First, Dr. Hughes relied primarily on IQVIA LAAD data,[16] but this specific data set "does not purport to be comprehensive"; for example, "[n]ot all TPPs contribute data." Frank Reply Rpt. ¶ 71(b).

Second, the IQVIA LAAD data extends through August 2021 only, which is "only 11 months after the entry of generic Truvada and Atripla and only 5 months after the entry of multiple generics." Frank Reply Rpt. ¶ 71(c); *see also* Frank Reply Rpt. ¶ 79. But "[t]he damage period would extend many more months beyond the generic entry date" – as many as 24-40 months. Frank Reply Rpt. ¶ 71(c).

Third, Dr. Hughes does not sufficiently address Dr. Frank's contention that, given the shortcomings of the LAAD data, "[t]he best available indicator of the percentage of patients who would have purchased the brand Truvada or Atripla after generic entry but never taken the generic versions of these drugs is the actual generic conversion rate calculated using the [IQVIA] Xponent data."[17] Frank Reply Rpt. ¶ 80. This data shows that, "by 17 months after generic entry, only 2% of Atripla molecule pills and 3% of Truvada molecule pills were the brand version." Frank Reply Rpt. ¶ 80. In his report, Dr. Hughes points out that "[t]he rate calculated by Dr. Frank is not a calculation of the percentage of *persons* taking the brand product who switch to the generic product, but instead represents only the ratio of the total *unit sales* of the generic equivalents of a brand product to the total sales of the brand plus its generic equivalents." Hughes Rpt. at 31 n.113 (emphasis added). This is true, but Dr. Hughes misses the point. The point is that, given certain shortcomings in the LAAD data, the Xponent data is a better proxy for purposes of assessing the likelihood of whether individual consumers would have purchased generic drugs over brand once

[16] "IQVIA . . . is a leading third-party provider of pharmaceutical sales data in the U.S. and globally; IQVIA data are commonly used in academic research, litigation, and strategic analysis conducted by firms such as Gilead, and is sometimes referred to as the 'gold standard' for pharmaceutical data." *See* Frank Rpt. at 23 n.107.

IQVIA offers various data products. "IQVIA LAAD data [is] a claims database that allows an analyst to follow the purchases of individual patients over time." Frank Reply Rpt. ¶ 54.

[17] Xponent is another product of IQVIA. Xponent "'measur[es] the retail outflow of prescriptions through the front door into the hands of consumers.'" *City of Huntington v. AmerisourceBergen Drug Corp.*, No. 3:17-01362, 2021 U.S. Dist. LEXIS 70336, at *12 (S.D. W. Va. Apr. 12, 2021).

the generics are available.[18]

As indicated by the Xponent data, with such a high generic conversion rate, it can reasonably be inferred that most TPPs would be injured because they would suffer injury from just one TPP member (individual consumer) buying generic over brand one time. Defendants try to argue, nevertheless, that brand loyalty at the TPP level is not uncommon. Dr. Hughes, the defense expert, asserts that, for "TPPs with only a few enrollees purchasing the at-issue drugs . . . [,] there is a higher likelihood . . . that brand loyalty at the consumer level will translate into brand loyalty at the TPP level." Hughes Rpt. ¶ 85. For example, if a TPP has just one member who buys the drugs at issue and that member is brand loyal, that essentially makes the TPP brand loyal as well. Dr. Hughes then notes there are, in fact, a significant number of TPPs who had just one member, or least ten or fewer members, who bought the relevant drugs. *See, e.g.*, Hughes Rpt. ¶ 86 & Fig. 13 (showing that, for Truvada, 6% of the TPPs had just one enrollee and 41% had ten or fewer; for Atripla, 29% of the TPPs had just one enrollee and 77% had ten or fewer); Hughes Rpt. ¶ 110 & Fig. 20 (showing that, for Complera, 36% of the TPPs had just one enrollee and 78% had ten or fewer).

Defendants' argument, however, is not well supported. Even if one puts aside the fact that Dr. Hughes was relying on a less-than-complete data set, *see* Frank Reply Rpt. ¶¶ 71, 82, Dr. Hughes seems to assume that, *any* time there is a small number of enrollees in a given TPP, those enrollees would *all* choose brand. *Cf.* Frank Reply Rpt. ¶ 73. That seems an unlikely scenario. *See also* Frank Reply Rpt. ¶¶ 83-87 & Figs. 10-12 (using Dr. Hughes's figures to estimate the percentage of TPPs that would have *only* brand-loyal members). And notably, in his report, Dr. Hughes points to only a handful of TPPs whose members all stayed brand loyal, *i.e.*, did not switch to generic Truvada or Atripla after a generic version became available, *see* Hughes Rpt. ¶ 85 – and even this claim is subject to criticism. *See, e.g.*, Docket No. 1169-3 (Opp'n at 7 n.6) (in opposition to *Daubert* motion related to Dr. Frank, arguing that "there is no reason to believe that

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[18] The Court notes that, even where Dr. Hughes does rely on Xponent data in his report, he also seems to use a less-than-complete data set. *See* Frank Reply Rpt. ¶ 71(c) (noting that the Xponent data set used by Dr. Hughes goes through June 2021 only; Dr. Frank relied on more updated Xponent data through February 2022).

even these TPPs would be brand loyal in the but-for world[;] [e]ach example includes a plan member that took brand Truvada in the pre-generic entry period and then had *no purchases of either brand or generic* Truvada in the post-generic entry period," but "Dr. Hughes offers no reason to think that such members would not have purchased the generic in the but for world if it had been available") (emphasis added).

Defendants contend still that the data shows

> 10% of TPPs in the Truvada class and 20% of TPPs in the Atripla class *never reimbursed for a generic equivalent*; instead, these TPPs reimbursed exclusively for branded products even after generic entry, and thus could not have suffered any 'brand-generic injury' because brand loyalty by their members resulted in these TPPs being brand loyal as well.

Opp'n at 23 (emphasis in original); *see also* Hughes Rpt. ¶ 89. But similar to above, Dr. Frank points out that Dr. Hughes arrived at these figures using a limited data set:

> The primary flaw in his method is that the Xponent dataset he uses is not well suited to this analysis. The dataset covers only the first 9 months after the launches of generic Truvada and Atripla (October 2020 through June 2021), and for the first 6 months generic competition was weak because there was only one generic on the market. By contrast, in the but-for world, multiple generics launched in the first month, and multiple generics would have stayed on the market for the full duration of the damage period. By contrast, his Xponent dataset provides a very short timeframe for consumers to convert to the generic.

Frank Reply Rpt. ¶ 88. Dr. Frank made new calculations using the Xponent data set through February 2022: "For Truvada, it reduced the value from 10% to 6%, and for Atripla, it reduced the value from 20% to 11%." Frank Reply Rpt. ¶ 89. Thus, the number of uninjured TPPs is de minimis at best.

Faced with this problem, Defendants protest that there is another problem beyond the alleged 10-20% uninjured TPPs: "another 25% in the Truvada class and 53% in the Atripla class did not reimburse for anything – brand or generic – after generic entry, and thus there is no evidence showing that these TPPs would have reimbursed for a generic had it been available earlier in the but-for world." Opp'n at 23; *see also* Hughes Rpt. ¶ 91. Once again, Dr. Frank persuasively addresses this argument in his reply report: even if there were no purchases (brand or

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generic) after generic launch, predictions about what would have happened in the but-for world are still possible based on the generic conversion rate. Furthermore, even if there were no brand-generic injury, there would still be brand-brand injury. *See* Frank Reply Rpt. ¶¶ 90-91.

Finally, Defendants argue that individualized inquiries are required for brand-generic injury as to Complera: (1) 11% of the TPPs continued to reimburse for brand Complera only (*i.e.*, after generic launch) and (2) another 13% of the TPPs actually paid less for the brand than they would have paid for the generic (or rather, partial generic since only the TDF/FTC part of Complera could be made generic). *See* Opp'n at 24; *see also* Hughes Rpt. ¶¶ 110-11. With respect to (1), 11% is arguably still a de minimis number – *i.e.*, individualized inquiries would not predominate over common questions. As for (2), Dr. Frank notes that Dr. Hughes's claim "is driven entirely by how [he] chose to calculate the TPPs' price per prescription rather than price per pill." Frank Reply Rpt. ¶ 93.

> To resolve this, I replicated his analysis with one modification: I used the but-for generic price from my current analysis (which is calculated in terms of price per pill, Dr. Hughes' preferred method), and I also calculated the TPPs' brand Complera prices in terms of price per pill. After the modification, Hughes' analysis showed that only **0.7%** of TPPs in the Complera class paid a price per prescription for Complera that was lower than my estimated average price per prescription of the generic version of Complera in the same month in the but-for world.

Frank Reply Rpt. ¶ 93 (emphasis in original).

iii. Brand-Brand Injury

As noted above, the EPPs argue that, even if there were some brand loyal TPPs, they were still injured as a result of Defendants' anticompetitive conduct because they suffered brand-brand injury. Defendants criticize Dr. Frank's assessment of brand-brand injury because he calculated brand prices on a per-prescription basis rather than a per-pill basis. Defendants assert that a per-prescription methodology is misleading – *e.g.*, if a 90-day prescription for a brand drug costs $3,000 *before* generic launch and a 30-day prescription for a brand drug costs $1,000 *after* generic launch, then the per-pill price is the same, but the per-prescription approach would suggest a savings of $2,000. *See* Opp'n at 20-21. According to Defendants, once this correction is made, "the average prices of brand Atripla and Truvada . . . *do not decrease* after generic entry." Opp'n

at 21 (emphasis in original); *see also* Hughes Rpt., App. F (showing that the brand prices for Truvada and Atripla remained stayed roughly the same after generic launch in the real world).

But in his reply report, Dr. Frank explained why it was not unreasonable for him to calculate on a per-prescription basis. *See, e.g.*, Frank Reply Rpt. ¶ 25 ("[U]sing prescriptions as the unit of analysis in an aggregate damage analysis is reasonable because prescription sizes are fairly standardized. In some respects, using prescriptions as the unit analysis is preferable to using pills [because] co-pays are typically paid on a per-prescription basis, not a per-pill basis . . . ."). More important, Dr. Frank went on to make new calculations on a per-pill basis and found that there was in fact a price decline for the brand drugs. Dr. Frank explained why Dr. Hughes reached a different result in his analysis: "Part of the reason Dr. Hughes did not recognize these declines in price per pill is that he was using an older Xponent data set that ended in June 2021, and the price declines became more evident after that date. I conducted the analysis . . . using the updated Xponent data set that goes through February 2022." Frank Reply Rpt. ¶ 27; *see also* Frank Reply Rpt., Figs. 5-7 (showing the retail prices over time for Truvada, Atripla, and Trizivir (the "yardstick" drug for Complera), including after generic launch(es)).

iv. Generic-Generic Injury

Finally, with respect to generic-generic injury, Defendants' challenge consists in part of a repetition of some of the arguments above (*e.g.*, there is no generic-generic injury if a TPP purchased or reimbursed for a brand drug only after generic launch, and some TPPs did not buy either brand or generic after generic launch). For the reasons stated above, those arguments lack merit.

Defendants' remaining argument is that, where a TPP did purchase or reimburse for a generic,

> many (21% for Truvada, and 20% for Atripla) only did so after April 2021 – six months after generic entry, at a time when Teva's exclusivity period had expired and mass generic entry resulted in these generics reaching a floor price. Because generic prices had bottomed out, there is no reason to believe that any of these TPPs would have paid any less for the generics they reimbursed even if generic entry had occurred earlier.

Opp'n at 25; *see also* Hughes Rpt. ¶ 93.

In response, the EPPs acknowledge that this last argument has some validity – but only in part: "[G]eneric retail prices do not decline instantaneously when multiple generics enter. It takes time for prices to respond to generic competition, and generic retail prices continue to decline over time even when no new generics enter the market." Frank Reply Rpt. ¶ 96. According to the EPPs, the impact of the delayed generic entry for Truvada and Atripla "end[ed] sometime between May and August 2021, . . . and [they] have ended the damage period at that point and incorporated that into [the] damage calculations." Frank Reply Rpt. ¶ 97. It will be up to the jury to determine what is the appropriate date for damages to end. The only concern at this point is whether there will be individualized inquiries for the jury to make this determination. Defendants have made no such showing.

b. Medicare Part D

Defendants argue that, putting aside the EPPs' antitrust injury theories, individualized inquiries are required to assess whether a given TPP is actually injured because about 20 percent of the TPPs provided coverage to members under Medicare Part D and it is unlikely that TPPs offering Part D coverage suffered injury (with respect to such coverage). The Court is not persuaded.

"Medicare beneficiaries, primarily people aged 65 and older (as well as individuals with permanent disabilities under the age of 65), are offered prescription drug coverage through Medicare Part D, a federal program . . . ." Hughes Rpt. ¶ 41; *see al* Frank Rpt. ¶ 37(b). "Medicare Part D plans are offered through private insurers that have been contracted by the Federal Government to offer such plans." Hughes Rpt. ¶ 98. Roughly speaking, under Part D, the plan assesses the expected cost of prescription drugs for a plan member. The government *prospectively* pays the plan for the majority of the expected cost, and the plan member the remainder. Later, if the expected cost ends up being greater than the actual cost, the plan pays the government back some of what the plan was paid in expected cost. If the expected cost is less than the actual cost, then the plan has to pay for part of that difference and the government covers the rest. *See* Hughes Rpt. ¶¶ 98-101; Frank Reply Rpt. ¶ 111.

Defendants argue that, as a result of the above structure, any payment that a TPP makes for

a cART drug is typically covered through the prospective payment from the federal government/plan member – *i.e.*, the TPP is not injured. *See* Hughes Rpt. ¶ 102; *see also* Hughes Rpt. ¶ 97 (asserting that a "Part D TPP may end up not bearing any financial responsibility for the cost of drugs purchased by its enrollees"); Opp'n at 25-26 (arguing that "[a] Part D TTP only pays part of a drug's cost if its actual costs happen to exceed the cost that the federal government expects the TPP to incur"). Defendants add: "While most Part D TPPs would not pay any of their members' prescription costs, assessing whether a TPP used its own funds to pay for HIV medications requires individualized inquiry." Opp'n at 26 (emphasis in original).

The Court rejects Defendants' argument. As the EPPs note, "the prospective government payments [from the federal government/plan member] are not made at the point of purchase" for a prescription drug, Reply at 17, and thus, they are "not part of the drug purchase transaction." Frank Reply Rpt. ¶ 112. The prospective payments are, in effect, payments for insurance (*i.e.*, akin to premiums). *See* Frank Reply Rpt. ¶ 111. That the prospective payments serve as a set off against the amount the plan paid for the prescription drug does not mean that the plan was not injured in the first instance; this is true even if the entire cost of the prescription drug was covered by the prospective payments. Those payments to the plan do not negate the plan's injury when it paid putatively high supracompetitive prices. *Cf. Staley v. Gilead Scis., Inc.*, No. 19-cv-02573-EMC, 2022 U.S. Dist. LEXIS 44935, at *38 (N.D. Cal. Mar. 14, 2022) (rejecting Defendants' argument that "entitlement to reimbursement negates the fact of injury"; citing *In re Nexium Antitrust Litigation*, 777 F.3d 9 (1st Cir. 2015), for the principle that "'antitrust injury occurs the moment the purchaser incurs an overcharge, whether or not that injury is later offset'") (emphasis omitted).

4. Measurable Damages

The last element of an antitrust claim is measurable damages. *See Namenda*, 338 F.R.D. at 550. If damages are capable of measurement on a classwide basis, then there is no Rule 23(b)(3) predominance problem. Here, the EPPs have offered evidence that they can establish aggregate damages – hence, damages capable of measurement on a classwide basis. *See, e.g.*, Frank Rpt. ¶¶ 138-41. Although Defendants do not dispute that the EPPs will be able to offer evidence on

aggregate damages, they argue that there is still a damages problem for the EPPs based on *Comcast Corp. v. Behrend*, 569 U.S. 27 (2013). There, the Supreme Court held that

> a model purporting to serve as evidence of damages in [a] class action must measure only those damages *attributable* to [the class's asserted] theory [of antitrust injury]. If the model does not even attempt to do that, it cannot possibly establish that damages are susceptible of measurement across the entire class for purposes of Rule 23(b)(3).

Id. at 35 (emphasis added); *see also Namenda*, 338 F.R.D. at 551 (stating that, in *Comcast*, the Supreme Court held that "a damages estimate proffered by a plaintiff's expert must actually correspond to the specific theory of liability that plaintiffs advance").

In particular, Defendants argue that the EPPs have violated *Comcast* in two ways: one concerns pharmacy benefit managers ("PBMs") and the other concerns Janssen.

a. <u>Pharmacy Benefit Managers</u>

PBMs are involved in the payment process for prescription drugs. They are "positioned" in drug purchase transactions between the pharmacies and the TPPs. Specifically, a PBM pays a pharmacy for a given prescription "on behalf of the patient's TPP in an amount set by contractual terms between the PBM and the pharmacy." Happe Rpt. ¶ 26. The TPP then pays the PBM for the prescription "in an amount set by contractual terms between the TPP and the PBM." Happe Rpt. ¶ 26. The amount that the TPP gives the PBM "may or may not match the amount the PBM paid to the pharmacy." Hughes Rpt. ¶ 32; *see also* Happe Rpt. ¶ 27. "When the PBM charges the TPP more or less than it pays the pharmacy, this is known as 'spread-pricing,' and can be a source of revenue or loss to the PBM." Happe Rpt. ¶ 27.

In their papers, Defendants note that the EPPs have excluded PBMs from the Damages Classes. However, Defendants argue that the EPPs have still violated *Comcast* because they "offer no way to adjust claimed damages to remove any overcharges paid by the PBMs." Opp'n at 31.

In response, the EPPs argue that, even though PBMs are involved in the payment process, they are just "service providers who process, adjudicate and make payment for prescription drug purchase transactions on the TPPs' behalf, using the TPPs' funds." Craft Rpt. ¶ 72. The PBMs

are not "parties to the retail transactions reflected in the prescription data and do not consider themselves to be end-payors or to be paying for the prescription drug purchases of their TPP clients." Craft Rpt. ¶ 72. Accordingly, the EPPs assert that the PBMs do not have any "overcharges that must be removed from [their] damages." Reply at 19. The EPPs add that "[a]ny compensation arrangements negotiated between PBMs and their TPP clients, including discounts and so-called 'spread pricing' do not alter the price paid for a drug at the pharmacy." Reply at 19-20. *See, e.g.*, Craft Rpt. ¶ 76 (stating that, if spread is retained by a PBM, it is "not part of the drug cost, but rather payment from the TPP for services provided to it by the PBM[;] [t]he price reported in PBM claims data and data such as Symphony Health and Xponent is the actual pharmacy reimbursement [and] thus represents the true drug cost regardless of whether the PBM may have received slightly more from its client"); *see also* Craft Rpt. ¶ 73 (stating that, "[a]lthough PBM rebate guarantees [to their clients] are common, they are not specific to any particular drug or drug manufacturer; they are calculated retrospectively and they do not adjust the point-of-sale purchase price paid by the TPP"); Craft Rpt. ¶ 78 (stating that PBM "[d]iscount guarantees are applied across the board to brand drugs or generic drugs generally, not to specific drugs"). Finally, the EPPs note that, even if it is *theoretically* possible for a PBM to be overcharged as Defendants have suggested – *i.e.*, when the PBM pays more to the pharmacy for a drug than what its charges to the TPP – Defendants have not shown that that is anything more than speculation. As the EPPs' expert notes: "[A]ny speculation about the occurrence of negative spreads ignores the fact that PBMs are in charge of negotiating each side of the spread and would obviously make efforts to assure this never happens." Craft Rpt. ¶ 76.

Numerous courts have agreed with the EPPs' argument that compensation arrangements between PBMs and TPPs have no real bearing on what the cost of a prescription drug is for purposes of determining antitrust injury. *See Loestrin*, 410 F. Supp. 3d at 387-88 ("Defendants . . . take issue with Winkelman's opinion that PBMs do not pay any portion of the cost of the drugs at issue in this case. While Winkelman states that some PBMs contract with TPPs to provide rebate guarantees and spread pricing, . . . the Court is persuaded that this arrangement does not constitute payment for the drug."); *id.* at 405 ("[T]he Court is not persuaded that practices like

spread pricing and rebate guarantees pay for specific drugs or reflect PBMs absorbing risk for specific drugs."). The Court is inclined to agree but it need not make a dispositive ruling on that matter as a legal matter because, even if Defendants' legal position were accepted, they have not provided any concrete evidence that, in this case, PBMs have, in fact, suffered loss by charging TPPs less than what the PBMs paid the pharmacies. As the EPPs expert indicates, it seems unlikely that the PBMs would put themselves in this position and would actively take steps to ensure that that situation does not happen. *See also Lidoderm*, 2017 U.S. Dist. LEXIS 24097, at *105 ("[D]efendants criticize Singer's model for its failure to exclude damages born by the PBMs that resulted from the speculated failure of the PBMs to effectively negotiate rebates and set spread prices. However, as discussed above, there is *no evidence* either of these scenarios actually occurred to PBMs with respect to lidocaine patches. Defendants' speculation cannot defeat certification."). There is no evidence that the contrary happened.

b. Janssen

Defendants argue next that the EPPs violated *Comcast* because their expert, Dr. Frank, "has proffered only *aggregate* damages figures, and he has not even attempted to apportion those amounts either by defendant or alleged misconduct." Opp'n at 32 (emphasis in original). Defendants contend that this is a particular problem with respect to the Complera Class: "[W]hile the alleged Complera damages are attributable to two liability components – (1) the Gilead/Teva patent settlements and (2) the non-compete provisions in the Complera agreement – Janssen was not at all involved in Gilead's settlements with Teva." Opp'n at 32.

Here, the problem for Defendants is that the EPPs have claimed joint and several liability on the part of Gilead and Janssen. *See* Reply at 20 (arguing that "Janssen unlawfully agreed not to market a generic version of Complera *whenever* generic TDF/FTC became available, including in 2018 when it would have become available but-for Gilead's unlawful reverse payments to Teva") (emphasis in original). Although a jury might well reject the joint-and-several-liability theory, that is a matter that the Court cannot prejudge at this stage of the proceedings. *Cf. In re Modafinil Antitrust Litig.*, 837 F.3d 238, 262 (3d Cir. 2016) ("Plaintiffs' theory of liability is not that each individual [reverse-payment settlement] agreement caused an individual harm, such that a new

damages model would be required under *Comcast*. Instead, their theory of liability is that each individual agreement contributed to the market-wide harm, and that all five original defendants are jointly and severally liable for this harm as concurrent tortfeasors. This theory may ultimately be proven wrong, but it does match Plaintiffs' damages theory.").[19]

5. Summary

For the foregoing reasons, the Court finds that the EPPs have satisfied the predominance requirement of Rule 23(b)(3). And given the predominance of common issues, the Court finds that a class action is manageable for each Damages Class and that a class action is "superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). The Court is inclined to adopt the EPPs' proposal that trial be bifurcated into two phases – in essence, resolving all issues in Phase I, including liability and aggregate damages, but leaving damages allocation for Phase II – as this also enhances the manageability of the class action.

D. Rule 23(b)(2) – Injunctive Relief Classes

In addition to the three Damages Classes, the EPPs seek certification of three Injunctive Relief Classes: (1) the Evotaz Class; (2) the Prezcobix Class; and (3) the cART Foundation Drug Class. Unlike the Damages Classes, the Injunctive Relief Classes include individual consumers. In fact, the proposed class representatives for the cART Foundation Drug Class are individual consumers only.

The Evotaz Class relates to the BMS/Gilead drug Evotaz (ATV/COBI). Allegedly, BMS and Gilead entered into the Evotaz Agreement to protect BMS's drug ATV once its patent expired. In terms of relief, the EPPs seek to enjoin enforcement of the NGR in the Evotaz Agreement – *i.e.*, so that Gilead would not be stopped from marketing a generic version of Evotaz once the patent on ATV expires.

The Prezcobix Class relates to the Janssen/Gilead drug Prezcobix (DRV/COBI). Allegedly, Janssen and Gilead entered into the Prezcobix Agreement to protect Janssen's drug DRV once its patent expired. In terms of relief, the EPPs seek to enjoin enforcement of the NGR

[19] This ruling is not determinative of the consequences to the EPPs' damages claim should they not prevail on the issue of joint and several liability.

in the Prezcobix Agreement – *i.e.*, so that Gilead would not be stopped from marketing a generic version of Prezcobix once the patent on DRV expires.

The cART Foundation Drug Class relates to ten cART drugs:

(1) Atripla (a Gilead/BMS drug) (TDF/FTC/EFV);

(2) Biktarvy (a Gilead drug) (BIC/TAF/FTC);

(3) Complera (a Gilead/Janssen drug) (TDF/FTC/RPV);

(4) Descovy (a Gilead drug) (TAF/FTC);

(5) Genvoya (a Gilead/Japan Tobacco drug) (TAF/FTC/EVG/COBI);

(6) Odefsey (a Gilead/Janssen drug) (TAF/FTC/RPV);

(7) Stribild (a Gilead/Japan Tobacco drug) (TDF/FTC/EVG/COBI);

(8) Symtuza (a Gilead/Janssen drug) (TAF/FTC/DRV/COBI);

(9) Truvada (a Gilead drug) (TDF/FTC); and

(10) Viread (a Gilead drug) (TDF).

In terms of relief for the cART Foundation Drug Class, the EPPs ask for several injunctions:

(a) an injunction preventing enforcement of any NGRs that would otherwise prevent Gilead or Janssen from marketing generic versions of the cART Foundation drugs;

(b) an injunction requiring (i) Gilead to issue licenses to TAF, FTC, and COBI to any willing licensee seeking to market competing versions of Evotaz and Prezcobix and requiring (ii) Janssen to issue licenses to its third agents to any willing licensee;

(c) an injunction finding forfeiture of any NCE (new chemical entity) exclusivity that Defendants might have related to Vemlidy (TAF), Descovy, Odefsey, Genvoya, Symtuza, and any other FDCs that contain TAF;

(d) an injunction finding forfeiture of any 30-month stay under the Hatch-Waxman Act that Defendants might have related to Vemlidy, Descovy, Odefsey, Genvoya, Symtuza, and any other FDCs that contain TAF;

(e) an injunction requiring Gilead to issue licenses to TDF, TAF, and FTC to any

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willing licensee;

(f) an injunction barring Gilead from enforcing its '791 patent (*i.e.*, one of the patents related to the Gilead drug TAF).[20]

See Mot. at 32 & nn.70-71.

The EPPs ask for certification of each of the Injunctive Relief Classes pursuant to Rule 23(b)(2), which provides that a class action may be maintained if "the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole." Fed. R. Civ. P. 23(b)(2).

1. Standing

Defendants argue first that there is a standing problem for the Injunctive Relief Classes. For Article III standing, a plaintiff must show: (1) an injury in fact, (2) a sufficient causal connection between the injury and the conduct complained of (*i.e.*, traceability), and (3) a likelihood that the injury will be redressed by a favorable decision. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). In the case at bar, Defendants focus on the factors of injury in fact and redressability.

a. Injury in Fact

As indicated above, the Injunctive Relief Classes are made up of both TPPs and individual consumers. Some of the proposed class representatives are individual consumers. *See generally* Docket No. 991-3 (listing proposed class representatives). According to Defendants, the proposed class representatives that are individual consumers lack standing to assert any claims because they are not currently suffering or likely to suffer an injury in fact.

As an initial matter, the Court notes that this argument has no impact at all on the Evotaz Class because the EPPs have proposed TPPs only as class representatives (Teamsters and

[20] At this juncture, Defendants are not making a challenge to the propriety of the injunctive relief sought by the EPPs. *See, e.g.*, Opp'n at 35 ("[l]eaving aside the impropriety of [a] request" that Gilead be compelled to forfeit "its lawfully-obtained regulatory and patent exclusivities").

BCBSA[21]), not consumers.

The argument also has no real impact on the Prezcobix Class because the EPPs have proposed as class representatives four TPPs (Teamsters, Local 1, FOP, and BCBSA) and only one individual consumer (Brenda Emily Goodrow). In other words, even if Ms. Goodrow lacked standing to proceed, the TPPs would not be affected. In any event, Ms. Goodrow has standing with respect to Prezcobix. *See* Miranda Decl. ¶ 18 ([redacted]).

The argument, however, does have potential impact on the cART Foundation Drug Class because, there, only individual consumers have been proposed as class representatives: Ivy Kwan Arce, Gregg Gonsalves, Ms. Goodrow, Joshua McDonald, Andrew Spieldenner, and Troy Vasquez-Cain. Accordingly, the focus here will be on the cART Foundation Drug Class.

As noted above, there are ten drugs that are related to this class:

(1) Atripla. None of the six individual consumers currently takes the drug. Some did take the drug in the past: [redacted] (2005); [redacted] (2011-2017); and [redacted] (2011-2016). *See* Miranda Decl. ¶¶ [redacted]

(2) Biktarvy. [redacted] currently takes the drug today. *See* Miranda Decl. ¶ [redacted]

(3) Complera. None of the six individual consumers currently takes the drug. [redacted] did take the drug in the past (2012-2016). *See* Miranda Decl. ¶ [redacted]

(4) Descovy. None of the six individual consumers currently takes the drug. In addition, none took the drug in the past.

(5) Genvoya. None of the six individual consumers currently takes the drug. [redacted] did take the drug in the past (2017-2019). *See* Miranda Decl. ¶ [redacted]

(6) Odefsey. Two individual consumers currently take the drug: [redacted] and [redacted]. *See* Miranda Decl. ¶¶ [redacted]

(7) Stribild. None of the six individual consumers currently takes the drug. [redacted]

[21] As noted above, BCBSA has been dismissed from the suit.

[redacted] did take the drug in the past (2014-2017). *See* Miranda Decl. ¶ [redacted].

(8) Symtuza. None of the six individual consumers currently takes the drug. In addition, none took the drug in the past.

(9) Truvada. None of the six individual consumers currently takes the drug. [redacted] did take the drug in the past (2015). *See* McDonald Decl. ¶ [redacted].

(10) Viread. None of the six individual consumers currently takes the drug. In addition, none took the drug in the past.

As indicated by the above, the drugs basically fall into three categories:

(a) The drug is currently being taken by some of the individual consumers.

(b) The drug is not currently being taken, but in the past was taken by some of the individual consumers – usually several years earlier.

(c) The drug has never been taken by any of the individual consumers – either currently or in the past.

Clearly, the drugs in categories (b) and (c) present concern with respect to standing. *See McGee v. S-L Snacks Nat'l*, 982 F.3d 700, 709 (9th Cir. 2020) ("A plaintiff threatened with future injury has standing to sue if the threatened injury is certainly impending, or there is a substantial risk that the harm will occur. And we have consistently held that a credible threat of future harm is sufficient to establish an injury in fact."). For these drugs, there is no indication that any individual consumer will likely take the drug in the future, even if he or she had taken the drug in the past (usually several years earlier).

That being said, there *are* drugs that are currently being taken by some of the individual consumers: Biktarvy ([redacted]) and Odefsey ([redacted]). These three individuals do have standing – and standing to represent the cART Foundation Drug Class, notwithstanding the fact that they have taken only two out of the ten drugs defined as cART Foundation Drugs. There is nothing to indicate on this record that these individuals cannot represent the broader class even if they are not currently taking or likely to take in the future most of the cART foundation drugs. For example, because [redacted] takes Biktarvy (a TAF-related drug), he is, absent contrary evidence, able to "represent" the other TAF-related drugs.

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Similarly, because [redacted] take Odefsey, they are able to "represent" the other drugs involved in the NGRs. There is no evidence of material dissimilarities between the "represented" and other drugs for purposes of the relief sought.

b. Redressability

i. Evotaz and Prezcobix Classes

As noted above, for the Evotaz and Prezcobix Classes, the EPPs seek an injunction barring enforcement of the NGRs in the Evotaz and Prezcobix Agreements. In theory, this injunctive relief would allow Gilead to enter the market with generic versions of Evotaz and Prezcobix.

Defendants contend that the EPPs lack standing to seek this injunctive relief because of a redressability problem – *i.e.*, a decision favorable to the EPPs would not likely redress the injury asserted. According to Defendants, this is because there is no indication that "an injunction *would result* in Gilead selling generic-based versions of [the drugs]," and, although the "EPPs suggest that Gilead may license a generic manufacturer to sell a generic version . . . , they fail to establish any likelihood that a generic-based version would come to market" – particularly for Prezcobix (DRV/COBI) since Janssen's patents on DRV last until 2026. Opp'n at 34 (emphasis added). Defendants add that, even if generic drugs were manufactured, there is nothing to show that (1) they would be cheaper, (2) insurance companies would cover them, or (3) patients would switch to them. *See* Opp'n at 34.

Defendants' position is not convincing. First, as the EPPs point out, a plaintiff's burden to show redressability "is 'relatively modest'": a plaintiff is not required to show it is guaranteed that a favorable decision will redress the plaintiff's injuries; rather, the plaintiff "need only show that there would be a 'change in legal status,' and that a 'practical consequence of that change would amount to a significant increase in the likelihood that the plaintiff would obtain relief that directly redresses the injury suffered.'" *Renee v. Duncan*, 686 F.3d 1002, 1013 (9th Cir. 2012). Here, there would be a change in legal status if the Court were to issue an injunction barring enforcement of the NGRs. And the EPPs have provided evidence – specifically, the opinion of an expert, Dr. Daniel Rubinfeld – that a practical consequence of that change would amount to a significant increase in the likelihood that a generic version of each drug would come to market. In

his report, Dr. Rubinfeld explains as follows:

> 17. *But-for the NGRs, a reasonable, profit-maximizing firm would have launched a competing generic version of the FDCs created by the collaboration agreements.* The NGRs prevented, and continue to prevent, any AB-rated competition to the FDCs developed pursuant to the collaboration agreements. There is, however, a variety of evidence showing that, but for the NGRs, reasonable profit-maximizing firms in the position of the collaboration partners would launch competing AB-rated versions of the FDCs. To elaborate, the collaboration partners would have strong incentives to develop and launch, or partner with generic manufacturers to develop and launch, AB-rated versions of the Covered Products. The products developed under the collaboration agreements have substantial sales, and the collaboration partner could earn substantially higher revenues outside the collaboration agreement. Furthermore, AB-rated versions have relatively low development, manufacturing, and marketing costs.
>
> 18. There is a variety of evidence suggesting that Defendants considered the launch of an AB-rated competitor a real threat, providing further support that a reasonable profit-maximizing firm would launch. First, the NGRs themselves suggest a belief on the part of Defendants that AB-rated competition was plausible. Second, internal documents from Defendants describe their concern about the prospect of competition from AB-rated versions of the products developed under the agreements. Third, both Janssen and Gilead did consider collaborating with generic manufacturers to develop FDCs.

Rubinfeld Rpt. ¶¶ 17-18; *see also* Rubinfeld Rpt. ¶¶ 114-31 (going into further details regarding the above). The Court finds the Rubinfeld report credible.

To the extent Defendants point out that Gilead could not launch (or enable a launch of) a generic version of Prezcobix (DRV/COBI) until Janssen's patents on DRV expire in 2026, that may be true. But that is beside the point since there is (as alleged) an illegal agreement *now*. As the EPPs note, the NGR is memorialized in the Prezcobix Agreement. And given that there are similar NGRs in other Gilead agreements that (as alleged) are already causing competitive harm, it makes little sense to require the EPPs to "wait until some undefined point in the future to start another lawsuit to challenge the same restraint[] on Prezcobix." Reply at 22.

Second, Defendants' contention that there is nothing to show that any generics – if manufactured – would be cheaper, would be covered by insurance companies, or would be

switched to by consumers is weak. Dr. Frank's report details how generic drugs upon launch are priced at a discount compared to the brand drugs and that there are high generic conversion rates – including for cART drugs in particular. *See, e.g.*, Frank Rpt. ¶ 81 (considering six cART drugs, including Truvada, Atripla, and Viread; noting that, "[i]n every case, the generic discounts are significant, and a greater number of generic competitors is associated with greater generic discounts"); Frank Rpt. ¶ 95 (stating that "[d]ata from the launches of generic versions of cART drugs shows that rapid generic conversion occurs for these drugs"). Dr. Rubinfeld's report also addresses how generic entry would lead to savings for TPPs and consumers alike. *See, e.g.*, Rubin Rpt. ¶¶ 96-111. These reports address and provide sufficient evidence of the likelihood of redressability of relief.

ii. cART Foundation Drug Class

For the cART Foundation Drug Class, Defendants essentially make the same redressability argument for other drugs that were involved in Gilead agreements containing NGRs (*e.g.*, Truvada, Viread, Atripla, Complera, Odefsey, and Symtuza). The Court does not find that argument persuasive.

This leaves the following cART Foundation Drugs which are not implicated in any NGR:

- Biktarvy (a Gilead drug) (BIC/TAF/FTC);
- Descovy (a Gilead drug) (TAF/FTC);
- Genvoya (a Gilead/Japan Tobacco drug) (TAF/FTC/EVG/COBI);
- Stribild (a Gilead/Japan Tobacco drug) (TDF/FTC/EVG/COBI);

For these drugs, Defendants suggest that there is no basis to seek an injunction. The Court does not agree. Biktarvy, Descovy, and Genvoya include TAF as a component, and thus these drugs are relevant to the EPPs' assertion that Gilead engaged in anticompetitive conduct through its development/commercialization of TAF. Contrary to what Defendants suggest, the EPPs have not abandoned this theory of anticompetitive conduct.[22] Stribild would also be part of the mix here because it is part of the narrative of moving consumers from TDF-based drugs to TAF-based

[22] The Rubinfeld report goes into the TAF development/commercialization theory. *See* Rubinfeld Rpt. ¶¶ 184-203, 205.

drugs. The Court acknowledges that Stribild and Genvoya are Gilead/Japan Tobacco drugs and the Court dismissed the claims the EPPs brought against Japan Tobacco. However, that dismissal essentially concerned removing the NGR theory out of the picture for these drugs. It did not concern and hence does not preclude the EPPs from relying on these drugs as part of the TAF development/commercialization theory.

For Biktarvy, Descovy, Genvoya, and Stribild (as well as all cART Foundation Drugs), the EPPs articulate an additional theory that supports injunctive relief – *i.e.*, that supracompetitive prices for a given cART drug puts upward pricing pressure on all other Gilead cART drugs (as discussed in the McGuire expert report). *See, e.g.*, McGuire Rpt. ¶ 204 ("Gilead's ordinary-course-of-business documents regularly report the extent to which sales displaced from some of its HIV drugs flow to its other HIV drugs. Gilead analyses have consistently found that 70-90% of switches out of Gilead drugs are recaptured by other Gilead drugs."); McGuire Rpt. ¶ 132 ("Gilead will price each drug in recognition that a sale lost due to a price increase is partially recaptured by sales diverted to the other product, putting upward pressure on price.").

2. Primary Relief

Finally, Defendants argue that it is improper to include Truvada, Atripla, and Complera as part of the cART Foundation Drug Injunctive Relief Class because "'Rule 23(b)(2) certification is inappropriate where the primary relief sought is monetary'" – which must be the case here given that the EPPs seek certification of three Damages Classes based on these drugs. This argument lacks merit because "there is a difference between seeking damages for a class certified under Rule 23(b)(2) and seeking to certify *separate* classes in the same action in which injunctive relief is sought for classes certified under Rule 23(b)(2) and damages are sought for classes certified under Rule 23(b)(3)." *Roy v. Cty. of Los Angeles*, No. 12-CV-09012-BRO-FFMX, 2016 U.S. Dist. LEXIS 186634, at *16 (C.D. Cal. Sept. 9, 2016) (emphasis added); *see also In re Qualcomm Antitrust Litig.*, 328 F.R.D. 280, 319 (N.D. Cal. 2018) ("Courts have approved the practice of 'certify[ing] the injunctive aspects of [a] suit under Rule 23(b)(2) and the damages aspects under Rule 23(b)(3), achieving both consistent treatment of class-wide equitable relief and an opportunity for each affected person to exercise control over the damages aspects.' Indeed, the

Ninth Circuit has recognized that Rule 23(b)(2) and Rule 23(b)(3) 'are not mutually exclusive.' Accordingly, courts in this district have certified classes under both Rule 23(b)(2) and Rule 23(b)(3) in antitrust suits where defendants' conduct 'was market-wide and not specific to individual customers.'"); *Feller v. Transamerica Life Ins. Co.*, No. 2:16-cv-01378-CAS-AJW, 2017 U.S. Dist. LEXIS 206822, at *26-27 (C.D. Cal. Dec. 11, 2017) ("[T]he Ninth Circuit has indicated that a district court can separately certify an injunctive relief class and, if appropriate, also certify a Rule 23(b)(3) damages class."); *cf. In re Kind LLC "Healthy & All Nat. " Litig.*, 337 F.R.D. 581, 609 (S.D.N.Y. 2021) ("Courts in this district have certified injunctive classes for consumer class actions, notwithstanding certification of additional classes seeking monetary damages.").

E. Class Certification Summary

For the foregoing reasons, the Court grants in part and denies in part the EPP motion for class certification.

- The Court does not certify any Damages Classes based on the laws of Arkansas, Idaho, Illinois, and Montana. The EPPs have not brought any antitrust claims based on the laws of these states (in the operative complaint), and the consumer protection claims based on the laws of these states lack merit and therefore are dismissed.
- The Court otherwise certifies the three Damages Classes and the three Injunctive Relief Classes but notes that certification for the Damages Classes shall be with respect to only those remaining repealer states that are actually identified in the state antitrust and consumer protection claims (fewer than 35 total). *See* note 5, *supra*.
- The Court appoints the proposed class representatives, as requested by the EPPs, except that, for the cART Foundation Injunctive Relief Class, the only class representatives that are approved are Mr. McDonald, Mr. Spieldenner, and Mr. Vasquez-Cain.
- The Court appoints as counsel for the Classes the current counsel representing the

EPPs.

The parties are ordered to meet and confer regarding the following: (1) new class definitions consistent with the Court's rulings above; (2) the special notice to be given to the local government entities; and (3) the content of a class notice and the timing for the notice. The parties shall report back on their meet-and-confer efforts within two weeks of the date of this order.

F. *Daubert* Motions

With respect to the EPP motion for class certification, Defendants challenged two of the EPP experts on *Daubert* grounds: Ms. Craft and Dr. Frank. For the reasons discussed below, the Court concludes that the opinions of both experts are sufficiently reliable and admissible – and were properly considered in the Court's analysis above for the motion for class certification.

1. Ms. Craft

In her report, Ms. Craft notes that she was hired by the EPPs to evaluate whether, "given the Proposed Class definitions and their various exclusions, it is possible to identify the included Class Members." Craft Rpt. ¶ 2. She concluded that it is possible.

> Doing so can be accomplished through a largely programmatic set of coding processes, employing [electronic] data legally required to be recorded and maintained in the highly regulated prescription drug industry. This electronic data is generated at the time each individual prescription is filled and identifies the payor as well as the exact price paid. The data is maintained by, and available from, multiple sources including pharmacies, Pharmacy Benefit Managers, switch operators who route the data, and TPPs themselves. The data is also collected in real time by commercial data publishers such as IQVIA and Symphony Health who sell the data to drug manufacturers (including defendant Gilead), managed care organizations and industry analysts.

Craft Rpt. ¶ 2; *see also* Craft Rpt. ¶ 11. Ms. Craft's specific opinions start at ¶ 10 of her report.

As indicated by the above, the EPPs have relied on Ms. Craft's report to argue that they have identified *ascertainable* classes – with ascertainability meaning "a class definition is precise enough for the court to determine membership by reference to objective criteria." EPP Mot. at 22.

According to Defendants, the Court should exclude Ms. Craft's opinions "regarding identification of EPP class members using pharmaceutical claims data" because it is unreliable. Daubert Mot. at 5. Defendants' main contention is that her opinions are unreliable because she

never performed her proposed methodology to actually identify the EPP class members or make the class exclusions. *See* Daubert Mot. at 3.

Defendants' motion is problematic for several reasons. First, the Ninth Circuit has expressly held that it has

> never interpreted Rule 23 to require . . . a showing [that there is an administratively feasible means of identifying absent class members], and, like the Sixth, Seventh, and Eighth Circuits, we decline to do so now. A separate administrative feasibility prerequisite to class certification is not compatible with the language of Rule 23. Further, Rule 23's enumerated criteria already address the policy concerns that have motivated some courts to adopt a separate administrative feasibility requirement, and do so without undermining the balance of interests struck by the Supreme Court, Congress, and the other contributors to the Rule.

Briseno v. ConAgra Foods, Inc., 844 F.3d 1121, 1123 (9th Cir. 2017); *see also id.* at 1127 (noting that "Rule 23's enumerated criteria [in particular, manageability] already address the interests that motivated the Third Circuit [in imposing an ascertainability requirement] and, therefore, that an independent administrative feasibility requirement is unnecessary.").[23]

Furthermore, the Ninth Circuit also stated in *Briseno* that "requiring class proponents to satisfy an administrative feasibility prerequisite 'conflicts with the well-settled presumption that courts should not refuse to certify a class merely on the basis of manageability concerns.'" *Briseno*, 844 F.3d at 1128 (adding that "[t]his presumption makes ample sense given the variety of procedural tools courts can use to manage the administrative burdens of class litigation[;] [f]or example, Rule 23(c) enables district courts to divide classes into subclasses or certify a class as to only particular issues").

Because the Ninth Circuit does not have an administrative feasibility/ascertainability requirement as a part of class certification, Ms. Craft's opinion is not necessary to the EPPs' motion for class certification. Thus, Defendants' motion to exclude Ms. Craft's opinion is moot.

Even if Ms. Craft's opinions on administrative feasibility were relevant, the ascertainability requirement (to the extent there is one), would simply ask that a plaintiff show the

[23] In *Briseno*, the Ninth Circuit technically "refrain[ed] from referring to 'ascertainability' . . . because courts ascribe widely varied meanings to that term." *Briseno*, 844 F.3d at 1124 n.3.

following:

> (1) the class is "defined with reference to objective criteria"; and (2) there is "a reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition." The ascertainability requirement consists of nothing more than these two inquiries. *And it does not mean that a plaintiff must be able to identify all class members at class certification – instead, a plaintiff need only show that "class members can be identified."*

Byrd v. Aaron's Inc., 784 F.3d 154, 163 (3d Cir. 2015) (emphasis added). Thus, Defendants' criticism that Ms. Craft did not actually apply her methodology to identify class members and exclusions is beside the point. Ms. Craft has a sound evidentiary basis for her methodology. *See* Opp'n at 3 (noting that Ms. Craft describes "how real-time prescription pharmacy data is maintained by, and available from, multiple sources including pharmacies, Pharmacy Benefit Managers ('PBMs'), switch operators who route the data, and TPPs themselves[;] [t]he data is also collected in real time by commercial data publishers such as IQVIA and Symphony Health who sell the data to drug manufacturers *including defendant Gilead*") (emphasis added). There is no requirement that she actually apply it to satisfy *Daubert*. *Cf. Carrera v. Bayer Corp.*, 727 F.3d 300, 306 (3d Cir. 2013) (stating that "[a] plaintiff may not merely propose a method of ascertaining a class without any evidentiary support that the method will be successful");

Several courts have specifically rejected the argument made by Defendants. *See, e.g.*, *Loestrin*, 410 F. Supp. 3d at 386 (stating that Ms. Craft's methodology to identify class members and apply exclusions, "while no doubt labor and time intensive, is not so different from the sort of aggregate data manipulation and analysis that businesses, researchers, and governmental agencies employ regularly"; "[w]hile it is true that Craft and OnPoint have never performed the exact task proposed here, Craft's Declaration, Sur-Rebuttal Report, and *Daubert* hearing testimony have demonstrated that the EPPs, subpoenas in hand, are capable of securing, compiling, and analyzing the requisite data to identify class members and apply the class exclusions"); *In re Namenda Indirect Purchaser Antitrust Litig.*, No. 1:15-cv-6549, 2021 WL 100489, at *12 (S.D.N.Y. Jan. 12, 2021) (noting that "Defendants . . . take issue with the fact that Craft has yet to use her methodology to ascertain exactly who is in the class [but] [t]hat does not render her methodology

unreliable[;] [i]t just means that, prior to knowing whether a class would be certified, class counsel has not expended the time and effort (and money) needed to identify all of its members").

The Court denies Defendants' motion to exclude Ms. Craft's opinions.

2. Dr. Frank

In his expert report, Dr. Frank provided opinions regarding, *inter alia*, antitrust injury/impact with respect to the EPP Classes. Defendants make a number of *Daubert* challenges to Dr. Frank's opinions, many of which replicate arguments addressed above. At bottom, Defendants have made arguments that affect the weight to be given Dr. Frank's opinions, and not their admissibility. Dr. Frank's methodology and application thereof are sufficiently reliable such that his opinions may properly be considered.

a. Brand-Generic Injury: "Switching"

Defendants argue that Dr. Frank's opinions on brand-generic injury are not reliable because (1) "[b]rand-generic injury only exists when a TPP has members who switched from a brand to an AB-rated generic equivalent and paid less for the generic medicine," but (2) "the 'generic conversion rates' presented by Dr. Frank do not measure the rate at which TPP's members switch" and instead are "more akin to brand and generic drug shares at any point in time." Daubert Mot. at 3.

This argument is not persuasive. First, as the EPPs point out, "[n]o case has rejected the use of generic market share to model the share of prescriptions that would have been generic." Opp'n at 6-7. The data showing brand and generic drug shares provide a reasonable basis from which to infer conversion. Second, as the EPPs suggest, Defendants have failed to explain why the generic conversion rate cannot be used to estimate who would have taken a generic in lieu of brand in the but-for world. In fact, Dr. Frank's report indicates that it is likely more accurate to use his generic conversion rate based on, *e.g.*, IQVIA Xponent data instead of Dr. Hughes's numbers based on IQVIA LAAD data (*e.g.*, with respect to LAAD, not all TPPs contribute data and data extends through August 2021 only). *See* pages 41-42, *supra*.

b. Brand-Generic Injury: Individualized Assessments

Defendants contend that Dr. Frank's opinions on brand-generic injury are also unreliable

because, in essence, he did not make individualized assessments. For example:

- "Dr. Frank does not examine any individual TPP data to determine whether and to what extent some TPPs may not have any members who converted [to generics]" – especially the smaller TPPs who have a smaller number of members. Daubert Mot. at 4.
- Even though states have different laws on the substitution of generics for brand drugs (*e.g.*, some laws make substitution mandatory while other laws make substitution permissive), "Dr. Frank simply assumes that most pharmacies and PBMs, irrespective of the type of substitution law in effect where they are located, are making substitutions." Daubert Mot. at 5.
- Even though "physicians can instruct pharmacists to fill a prescription without generic substitution using a 'dispense as written' ('DAW') designation," Dr. Frank did not "examine the prevalence of DAW designations with HIV medications" and instead simply "speculates that, based of his generic penetration rates, the percentage of DAW designations" was low. Daubert Mot. at 5.
- Even though a generic drug would not necessarily be "placed on a more favorable formulary tier than the brand counterpart" (*i.e.*, "there is variation with respect to prescription drug placement on formularies between commercial payors, within commercial payors, and between commercial payors and Medicare"), "Dr. Frank dd not examine actual formularies to confirm whether AB-rated generic HIV drugs, and in particular AB-rated generic versions of Atripla and Truvada, are always placed in a more favorable tier than their brand counterparts [which would encourage use of generics over brand drugs]." Daubert Mot. at 5.
- Dr. Frank did not conduct a "robustness check" to confirm the reliability of his model and that it could be used to show class-wide injury. Daubert Mot. at 5.

While the above is fair game for cross-examination of Dr. Frank, the question at this point is whether Dr. Frank's opinions on brand-generic injury are so unreliable that they should not even be admissible in the first place. Given the high generic conversion rates, Dr. Frank's opinions

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have a sufficiently sound basis even if he did not make individualized assessments. *See* Frank Reply Rpt. ¶ 44. As the EPPs argue, the high average generic conversion rates imply a low likelihood that any TPPs will have zero prescriptions that would be converted to the generic. Dr. Frank based his opinions on conversion rates over 90% and basic probability concepts.

c. Price Calculations: Retail Prices

Defendants next contend that Dr. Frank's price calculations (used to show antitrust injury/impact) are unreliable because he used IQVIA Xponent retail price data, and retail prices are not the same thing as prices paid by the TPPs. Defendants note that many parties can be involved in a pharmaceutical transaction – *e.g.*, the manufacturer, wholesaler, retail and mail-order pharmacy, consumer, insurer, PBM, third-party administrator, and/or administrative services only offeror. *See* Hughes Rpt. ¶ 26. According to Defendants, "[a]ny of these parties, or their arrangements with other parties, can affect the price paid by each TPP for a given prescription pharmaceutical. PBMs, in particular, offer multiple different benefits, including contractually mandated prices (which may or may not match the amount the PBM paid to the pharmacy), for the TPPs." Daubert Mot. at 8.

However, the EPPs have shown that using retail prices does not make Dr. Frank's price calculations unreliable. Dr. Frank explained that, "because of the high prices of these drugs, consumer cost sharing is a small fraction of the drug retail price, so offsets from cost-sharing would not eliminate the overcharge in any material number of transactions". Frank Rpt. ¶ 132(b). Regarding PBMs, Defendants are simply speculating that PBMs have been injured through negative spread pricing. Defendants provide no evidence of actual negative price spreading here.

d. Price Calculations: Price Per Prescription

Defendants also criticize Dr. Frank's price calculations as unreliable on the basis that he made price-per-prescription calculations as opposed to price-per-pill calculations. *See* Daubert Mot. at 9 (arguing that "'retail price per prescription' is not an appropriate metric because it does not account for differences in the number of days covered by the individual prescriptions" – "under Dr. Frank's methodology, if a class member paid for a 90-day supply prescription and then switched to three 30-day supply prescriptions that in total had the same cost, Dr. Frank would

erroneously conclude that the price had declined because he would compare the cost for the 90-day prescription to the cost of a single 30-day prescription”).

But in his reply report, Dr. Frank explained why it was not unreasonable for him to calculate on a per-prescription basis. *See* Frank Rebuttal Rpt. ¶ 25. Moreover, Dr. Frank went on to make new calculations on a per-pill basis and found that there was in fact a price decline for the brand drugs. Dr. Frank explained why Dr. Hughes reached a different result in his analysis: “Part of the reason Dr. Hughes did not recognize these declines in price per pill is that he was using an older Xponent data set that ended in June 2021, and the price declines became more evident after that date. I conducted the analysis . . . using the updated Xponent data set that goes through February 2022.” Frank Rebuttal Rpt. ¶ 27; *see also* Frank Rebuttal Rpt., Figs. 5-7 (showing the retail prices over time for Truvada, Atripla, and Trizivir (the “yardstick” drug for Complera), including after generic launch(es)). Dr. Frank had a reasonable and credible basis for his opinion. For purposes of the class certification motion, his analysis is more convincing than Dr. Hughes.

e. <u>Complera: Use of Trizivir as “Yardstick”</u>

Defendants challenge next the reliability of Dr. Frank’s opinions with respect to Complera. According to Defendants, Dr. Frank’s opinions on Complera are unreliable for two reasons:

(1) Dr. Frank assumes that “Janssen would have entered with a hybrid generic version of Complera – consisting of [Janssen’s] branded RPV, generic TDF and generic FTC – in the absence of the [NGR],” but “does nothing to substantiate the assumption. Absent a view on the prospect of entry by Janssen, or even an awareness of evidence about that prospect, Dr. Frank’s model of Complera injury and damages is fundamentally incomplete . . . .” Daubert Mot. at 12.

(2) Because there is no generic version of Complera yet available, Dr. Frank had to consider what the generic conversion rate would be using a yardstick drug. He chose Trizivir, but Trizivir is not an appropriate analog. While Trizivir contained *all* generic components, a generic version of Complera would be comprised of Janssen’s *branded* RPV and generic TDF/FTC. In addition, “Janssen has a direct financial stake in the sale of branded Complera” (because, even though Gilead sold

> Complera, it paid Janssen the equivalent of 70% of the RPV portion of the FDC), and therefore any sales by Janssen of generic Complera "would cannibalize the revenue from the branded product[.] [A]t the same time, any sales by Janssen of [generic Complera] in the but-for-world would presumably create the same 30% royalty obligation to Gilead that Janssen owed on the RPV portion of any sales of TDF/3TC/RPV in the actual world." Mot. at 13; *see also* Mot. at 12 (noting that Gilead contributed $100 million toward the development of RPV, and, "in consideration of that substantial investment . . . , Janssen owed Gilead [a] 30% share of RPV if the branded component was used by Janssen in a similar FDC consisting of TDF/3TC/RPV").

Neither argument is compelling enough to warrant exclusion under *Daubert*. On (1), the EPPs fairly note that "Dr. Frank may rely on what EPPs expect to prove at trial and other expert testimony that supports such proof [*i.e.*, that Janssen would make a generic version of Complera]." Opp'n at 12. *See, e.g.*, *In re Glumetza Antitrust Litig.*, 336 F.R.D. 468, 477 (N.D. Cal. 2020) (in response to defendants' argument that expert relied on factual assumptions and offered no evidence in support of the assumptions, stating that "[e]valuating whether common issues predominate antitrust impact requires us to assume class counsel will otherwise prove (by common evidence) the antitrust violation at trial[;] [s]o, Dr. Leitzinger assumes (as counsel directed): (i) Lupin would have entered the market (perhaps even 'at risk') in May 2012; (ii) Santarus would have promptly marketed an authorized generic; and (iii) the 2015 price hikes would not have occurred"). If there was no danger that Janssen would ever launch a generic version of Complera once TDF/FTC lost their patent protection, then the NGR should have been unnecessary. Hence, the existence of the NGR evidences the parties' intent, an intent not consistent with Dr. Frank's assumption.

As for (2), "'[t]he selection of comparators will seldom approach the "Utopian ideal" of identifying the perfect clone,'" and "'[a]rguments about what factors an expert should have controlled for in conducting a yardstick analysis generally go to the weight, rather than the admissibility, of the expert's testimony.'" *In re Suboxone*, 421 F. Supp. 3d 12, 43 (E.D. Pa.

2019); *see also Tawfilis v. Allergan, Inc.*, No. 8:15-cv-00307-JLS-JCG, 2017 U.S. Dist. LEXIS 122974, at *19 (C.D. Cal. June 26, 2017) (stating that expert's "yardstick methodology . . . is a reliable methodology for calculating damages and is admissible under Daubert and Rule 702[;] [a]rguments about what factors an expert should have controlled for in conducting a yardstick analysis generally go to the weight, rather than the admissibility, of the expert's testimony"). Defendants' argument goes to the weight, not admissibility, of this evidence. *See In re Prograf Antitrust Litig.*, No. 1:11-md-02242-RWZ, 2014 U.S. Dist. LEXIS 180899, at *10 (D. Mass. Dec. 23, 2014) (recognizing that "[a]ntitrust plaintiffs bear the 'burden of proving comparability' of their proposed yardstick to the but-for world," but evaluating factors on comparability "generally involves weighing facts, [and thus] deciding '[w]hether the plaintiff has met this burden of showing comparability ordinarily is a question for the trier of fact'"). Notably, Gilead itself used Trizivir as an analog for purposes of modeling the effects of generic entry. *See* Lamb Reply Rpt. ¶ 94.

Finally, as noted above, if there was no danger that Janssen would ever launch a generic version of Complera once TDF/FTC lost their patent protection, then the NGR should have been unnecessary. Gilead also does not provide any specifics on Janssen's potential "internal" competition – *e.g.*, even if Janssen would lose sales on brand Complera, would the pricing or volume of sales on the generic version compensate for that loss? *Cf.* Frank Reply Rpt. ¶ 18 (noting that, "because Janssen's generic Complera would be the only generic on the market, Janssen would have little incentive to apply very high discounts" to the generic price). Along those lines, Dr. Frank notes as follows in his reply report.

> [The defense expert] Dr. Hughes claims that Janssen would be making a profit on branded Complera in the but-for world and that this would amount to an opportunity cost on its sales of its generic version of Complera. He asserts that this opportunity cost would have a large impact on the generic price. He states, "The price a firm charges for a product depends on that firm's marginal cost: the higher the marginal cost, the higher the profit-maximizing price. . . . The profits lost from reduced sales of branded Complera are likely to be large and have a substantial impact on Janssen's marginal cost of selling a unit of a competing AB-rated product. Economic theory tells us that this additional and substantial component to marginal cost should result in a relatively higher price." Hughes' economic analysis of my work is flawed, since my analysis sees the market as

> a duopoly where Janssen's generic Complera would have some market power that implies the opportunity to recover their sunk costs.

Frank Reply Rpt. ¶ 19. Dr. Frank's reasoning and the bases therefore are sufficiently reliable to pass *Daubert* muster.

For the foregoing reasons, the Court denies the motion to exclude Dr. Frank's opinions. Defendants' arguments are relevant to the weight to be given Dr. Frank's opinions but not their admissibility. Dr. Frank's opinions are sufficiently reliable such that they may be considered on their merits, as applicable to the EPP motion for class certification.

IV. DPP MOTION FOR CLASS CERTIFICATION

The Court now turns to the second motion for class certification, which has been filed on behalf of the DPPs. KPH is the putative class representative for the DPPs. As pled in the operative complaint, KPH sought certification of the following direct purchaser class: "All persons in the United States and its territories who directly purchased cART drugs from Defendants from October 6, 2016 until the anticompetitive effect of Defendants' unlawful conduct cease." FAC ¶ 413.

However, in the pending motion for class certification, KPH has changed its request for certification. It now seeks to certify three Damages Classes:

(1) Truvada Class: "All persons or entities in the United States and its territories who purchased Truvada or generic Truvada directly from any of Defendants or any brand or generic drug manufacturer from February 1, 2018, until the date of the class certification order." DPP Mot. at 1-2.

(2) Atripla Class: "All persons or entities in the United States and its territories who purchased Atripla or generic Atripla directly from any of Defendants or any brand or generic drug manufacturer from February 1, 2018, until the date of the class certification order." DPP Mot. at 2.

(3) Complera Class: "All persons or entities in the United States and its territories who purchased Complera directly from any of Defendants from February 1, 2018, until the date of the class certification order." DPP Mot. at 2.

Although the Damages Classes are generally narrower in scope compared to the class as defined in the FAC, there is one aspect in which the Truvada and Atripla Classes are broader. In the class definition in the complaint, the class was limited to those who had purchased cART drugs (brand or generic) from *Defendants*. In the Truvada and Atripla Classes, KPH essentially seeks certification of those who purchased the drugs – not just from Defendants but from *any generic manufacturer*.

Because KPH settled the putative DPP class action against BMS, that now leaves Gilead as the only defendant. In opposing KPH's motion for class certification, Gilead makes two primary arguments: (1) the numerosity requirement in Rule 23(a) has not been satisfied and (2) the predominance requirement in Rule 23(b)(3) has not been satisfied.

A. Rule 23(a) Requirements

With respect to the Rule 23(a) requirements, Gilead does not seriously dispute that the following requirements have been met: commonality, typicality, and adequacy. Even if Gilead had disputed these elements, the Court would find these requirements met for each Class. Clearly, there are issues of fact and law in common because putative class members in each Class assert that Gilead engaged in commerce anticompetitive conduct. As for typicality and adequacy, nothing suggests that KPH's claims materially differ from those of other direct purchasers.

Defendants contest numerosity. Rule 23(a) provides class certification is appropriate if, *inter alia*, "the class is so numerous that joinder of all members is impracticable." Fed. R. Civ. P. 23(a)(1). "Impracticability does not mean impossibility, but only the difficulty or inconvenience of joining all members of the class." *Solodyn*, 2017 U.S. Dist. LEXIS 170676, at *10 (internal quotation marks omitted). As one treatise has explained:

> Three underlying concerns of the class action help explain Rule 23(a)(1)'s requirement that joinder be impracticable. *First*, the Rule reveals the legal system's preference that litigation be conducted by present, joined, individual litigants rather than by class representatives on behalf of absent class members. . . . The preference for individual joinder reflects American adjudication's general theory that individuals possess a due process right to litigate for themselves and that representative litigation is therefore an exceptional form of litigation. The insistence that those proposing representative litigation show that joinder is impractical therefore safeguards individual due process rights by insisting that individuals

> get to litigate themselves so long as it is practical for them to do so.6
>
> *Second*, the requirement that joinder of individual litigants be impractical helps ensure that proceeding in the class form is in fact an efficient means of adjudication. Where many individuals have similar claims, there may be a flood of litigation. With so many litigants proceeding individually, the courts would be overrun with claims. Yet the vast quantity of individual litigants makes joinder impracticable. The class action solves this problem because it "saves the resources of both the courts and the parties by permitting an issue potentially affecting every [class member] to be litigated in an economical fashion under Rule 23." Thus, where joinder is impracticable, judicial economy weighs in favor of representative litigation of common issues for similarly situated plaintiffs.
>
> *Third*, even if the courts are not flooded with numerous litigants, other factors may indicate that joinder would be impracticable and argue in favor of representative litigation. For instance, if individual claims are small and/or class members are financially unable to fund litigation themselves, individual joinder may be practically impossible.

Newberg and Rubenstein on Class Actions § 3:11 (6th ed.) (emphasis in original).

"Neither Rule 23 nor its accompanying Advisory Committee Notes provide a clear formula for determining when joinder of all members is impracticable." *Id.* Likewise, the Supreme Court has stated that the "'numerosity requirement requires examination of the specific facts of each case and imposes no absolute limitations.'" *A.B. v. Haw. State Dep't of Educ.*, 30 F.4th 828, 835 (9th Cir. 2022) (adding that, although the Supreme Court "thus eschew[ed] any bright-line rules, [it] did go on to state that a class with only 15 members 'would be too small to meet the numerosity requirement'"). That being said, the Ninth Circuit has articulated some general principles to help guide lower courts. For example, a court "must consider what the evidence shows concerning 'the absolute number of class members.'" *Id.* "Although the absolute number of class members is not the sole determining factor, where a class is large in numbers, joinder will usually be impracticable." *Jordan v. Cty. of L.A.*, 669 F.2d 1311, 1319 (9th Cir. 1982), *vacated on other grounds by Cty. of Los Angeles v. Jordan*, 459 U.S. 810 (1982).

Based on pure numbers alone, 40 class members is generally sufficient to meet the numerosity requirement. *See id.*; *see also Tait v. BSH Home Appliances Corp.*, 289 F.R.D. 466, 473 (C.D. Cal. 2012) (citing *Jordan* for the proposition that "[a] proposed class of at least forty members presumptively satisfies the numerosity requirement"). In contrast, "'[a] class of 20 or

fewer is usually insufficiently numerous . . . . Classes with between 21 and 40 members are given varying treatment." *Modafinil*, 837 F.3d at 250.

Importantly, the Ninth Circuit has noted that,

> where the size of the class is more modest, "the number of class members does not weigh as heavily" in the analysis, and "other factors" bearing upon the feasibility and convenience of joinder may assume more significance. These potentially countervailing factors include "the geographical diversity of class members, the ability of individual claimants to institute separate suits, and whether injunctive or declaratory relief is sought," as well as the ability to identify and locate class members.

A.B., 30 F.4th at 835-36.

In the instant case, KPH's expert, Dr. Russell Lamb, opines that there are:

(1) 78 members in the Truvada Class;

(2) 51 members in the Atripla Class; and

(3) 25 members of the Complera Class.

See Docket No. 1082-4 (Lamb Decl.) (revising original numbers submitted in his expert report).

Relying on its own expert, Dr. Bruce Strombom, Gilead argues that these numbers are inflated. Dr. Strombom asserts that Dr. Lamb should have excluded:

- from each of the three Damages Classes, **7-8 direct purchasers** because they filed individual actions in this Court (*i.e.*, Albertsons, CVS, HEB, Humana, Rite Aid, Kroger, United Health, and Walgreens);
- from the Truvada and Atripla Classes, 1-2 direct purchasers each because, even after generic launch of Truvada and Atripla, they continued to purchase the brand versions of the drugs and not generic;
- from the Truvada Class, **50 direct purchasers** and, from the Atripla Class, **24 direct purchasers**, because each one never purchased brand Truvada or Atripla at any point in time and, after generic launch, purchased only generic versions of the drugs;
- from each of the three Damages Classes, 2-3 direct purchasers because they were acquired by other putative class members.

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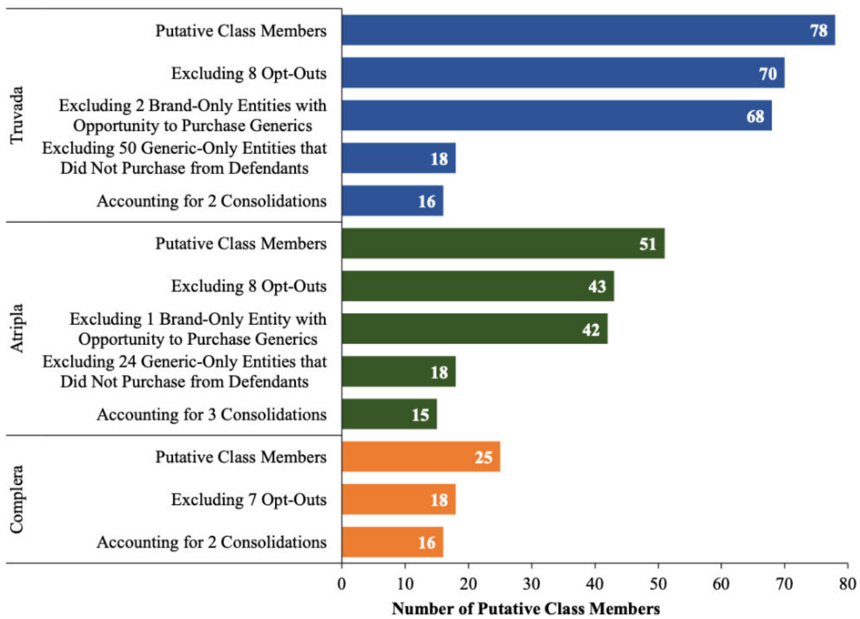
Below is a chart that reflects Gilead's position regarding exclusion on who should be excluded.

Figure 5
Maximum Number of Putative Class Members after Exclusions and Consolidations



Strombom Rpt. ¶ 44.

As indicated by the bolded information above, for purposes of the pending motion, the Court need only consider the first and third asserted exclusions – *i.e.*, likely opt-outs and generic-only entities that never purchased from Defendants – because only those exclusions have numbers of any significance.

1. <u>Individual Actions Filed by 7-8 Direct Purchasers</u>

Gilead's position is that any direct purchaser who filed an individual action should implicitly be counted as an opt out and therefore is not part of the class. KPH responds, in essence, that it is premature to say that a direct purchaser who has filed an individual action will be an opt out – *i.e.*, the opt-out determination cannot be made until after notice goes out to the class.

KPH has the better position. Although the direct purchasers who filed individual actions may well opt out, it is impossible to say for sure at this juncture.

Most courts have agreed with KPH's position – either explicitly or implicitly. *See, e.g.*, *Solodyn*, 2017 U.S. Dist. LEXIS 170676, at *22 ("declin[ing] to adopt Defendants' position that five purchasers' filing separate complaints compels the conclusion that they would opt-out of the class, if certified"); *Cromeans v. Morgan Keegan & Co.*, 303 F.R.D. 543, 551-52 (W.D. Mo. 2014) (recognizing that "some class members have initiated their own lawsuits, [but defendant] Morgan Keegan has not shown that the class members pursuing individual litigation will opt out of any class that is certified"); *MacNamara v. City of N.Y.*, 275 F.R.D. 125, 142 (S.D.N.Y. 2011) (noting that "Defendants supply no authority for the proposition that the existence of parallel actions should automatically reduce the number of prospective class members for purposes of the class certification inquiry[;] [u]nder Rule 23, individuals are considered class members until they opt out of the suit, and 'the mere possibility that members of a potential class may choose to opt out in the future is not enough to preclude a finding of numerosity'"); *see also Demint v. Nationsbank of Fla., N.A.*, 208 F.R.D. 639, 641 (M.D. Fla. 2002) (stating that "the mere pendency and continued prosecution of a separate suit, which the litigant instituted before commencement of the 'opt out' period in a related class action, neither registers nor preserves a litigant's election to 'opt out' of the related class action"); *In re Prudential Sec. Ltd. Pshps. Litig.*, 164 F.R.D. 362, 370 (S.D.N.Y. 1996) (stating that "'pendency of an individual action does not excuse a class member from filing a valid request for exclusion'").

Finally, several of the authorities that Gilead cites seem to give more support for KPH than Gilead; only those class members who actually opt out are excluded. For example, in *Bauman v. United States District Court*, 557 F.2d 650 (9th Cir. 1977), the Ninth Circuit indicated that class members who *actually* opt out might affect numerosity. *See id.* at 656 ("The order of the district court – specifically that portion permitting class members to opt out – may have the effect of reducing the size of the class. Alternatively, if sufficient people opt out, it may have the effect of foreclosing class certification. In either case, we must determine whether the damage to Bauman arising from the order is correctable on appeal."). The same was true in *Tasion Communications, Inc. v. Ubiquiti Networks, Inc.*, 308 F.R.D. 630 (N.D. Cal. 2015) (Chen, J.). *See id.* at 643 ("To the extent Plaintiffs argue that a putative class member can simply opt out to protect its interests,

that may be true, but it is then possible that a large number of putative class members would opt out, which could result in a numerosity problem.”).

Gilead’s best authority is *In re Zetia Ezetimibe Antitrust Litigation*, No. 2:18md2836, 2022 U.S. Dist. LEXIS 69566 (E.D. Va. Apr. 13, 2022). There, the court indicated that “seven retailer plaintiffs should not be considered for purposes of analyzing whether the putative class satisfies the requirements of Rule 23(a),” including numerosity, because they were “‘likely opt-outs.’” *Id.* at *20. But notably, the court also seemed to place stock in the fact that the DPPs had conceded the size of the class in appellate proceedings. *See id.* (citing to appellate decision); *see also In re Zetia (Ezetimibe) Antitrust Litig.*, 7 F.4th 227, 238 (U.S. 4th Cir. 2021) (noting that “Plaintiffs did not appeal the thirty-five-member class or argue the class should be a fifty-eight-person class that included the twenty-three dismissed companies” and “[f]ailure to do so constitutes waiver”). Therefore, although *Zetia* does support Gilead, that support is equivocal and not persuasive in view of the substantial authority supportive of KPH’s position.

2. No Purchases of Brand Drugs by 24-50 Direct Purchasers

The biggest exclusion that Gilead seeks is with respect to the Truvada and Atripla Classes. As noted above, Gilead contends that, from the Truvada Class, **50 direct purchasers** should not be counted and, from the Atripla Class, **24 direct purchasers**, because each one never purchased brand Truvada or Atripla at any point in time and, after generic launch, purchased only generic versions of the drugs.

KPH is essentially claiming generic-generic injury here. But the generic-generic injury it claims appears different from the generic-generic injury claimed by the EPPs. The EPPs seek to cover purchases/reimbursements with respect to (1) the brand drugs and (2) their generic equivalents *to the extent sold by Teva only*. Here, KPH essentially seeks to cover purchases with respect to (1) the brand drugs and (2) their generic equivalents *sold by any generic manufacturer* (*i.e.*, Teva or otherwise). *See* DPP Mot. at 1-2 (defining, *e.g.*, Truvada Class as “[a]ll persons or entities in the United States and its territories who purchased Truvada or generic Truvada directly from any of Defendants or any brand or generic manufacturer from February 1, 2018, until the date of the class certification order”).

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a. Procedural Challenge

As an initial matter, the Court notes that Gilead has launched a procedural challenge that would require exclusion of the direct purchasers at issue. Gilead notes that these direct purchasers never purchased any drugs *from Defendants*. That being the case, the direct purchasers do not meet the class definition contained in KPH's operative complaint. *See* FAC ¶ 413 ("All persons in the United States and its territories who directly purchased cART drugs *from Defendants* from October 6, 2016 until the anticompetitive effect of Defendants' unlawful conduct cease.") (emphasis added). Gilead concedes that the direct purchasers meet the new class definitions contained in KPH's motion – *i.e.*, because those class definitions cover purchases of Truvada/Atripla or their generic equivalents from Defendants or *from any generic manufacturer*. But Gilead argues that it is improper for KPH to expand the class definition at this late stage. *Cf. Namenda*, 331 F. Supp. 3d at 210 (stating that "[i]t is well-established that a certifying court 'is not bound by the class definition proposed in the complaint,'" but adding that "this principle is customarily cited as support for the court's ability to *narrow* a proposed class[;] [f]ar fewer cases support the converse proposition that the court may approve the expansion of the class as it was defined in the complaint") (emphasis added). Gilead points out that KPH never sought this "amendment" until October 20, 2021, when it filed the pending motion for class certification – which was only two months before fact discovery was due to close on December 17, 2021. *See* Docket No. 781 (order). Gilead maintains: "Had KPH timely obtained leave to amend, the targeted discovery sought from the non-party generic manufacturers earlier in the case would have been more extensive and focused on KPH's new generic-only purchaser theory, including inquiry into individual generic manufacturers' sales and marketing practices (e.g., pricing, rebates, discounts, and formulary placement)." Opp'n at 9.

Although Gilead's position is not without merit, it is not persuasive. "[A] plaintiff's expansion of the class definition beyond that which was proposed in the complaint is not categorically improper." *Namenda*, 331 F. Supp. 3d at 211. Rather, the court should consider whether the defendant would be prejudiced as a result of the expansion. *See id.* (noting that "Plaintiffs' proposed class definition does not raise the same notice and discovery issues present in

[another case]"). *Compare* Fed. R. Civ. P. 15(a)(2), *with* (b)(1) and (2). Here, it is true that KPH did not bring up the new class definitions until its motion for class certification was filed in October 2021, which was only two months before fact discovery closed. But Gilead never sought an extension of fact discovery because of this situation; it sought no relief from the Court. Moreover, both before the filing of the class certification motion and after, Gilead took discovery from a number of other generic manufacturers other than Teva. *See generally* Schork Decl. ¶¶ 12-28 (discussing discovery taken from generic manufacturers from July 2021 through December 2021 – with some discovery being initiated by KPH or the EPPs and some discovery being initiated by Gilead). Gilead suggests that it has been prejudiced because it would have taken more extensive discovery, "inquir[ing] into individual generic manufacturers' sales and marketing practices (e.g., pricing, rebates, discounts, and formulary placement)." Opp'n at 9. But Gilead ignores the fact that much of the third-party discovery took place *after* KPH filed its motion for class certification which put at issue KPH's proffered class definition.

b. Substantive Challenge

Gilead asserts that, even if there is no procedural problem, there is still a substantive reason to exclude the direct purchasers who never purchased any brand drugs (Truvada and Atripla) and instead only purchased generics. As noted above, KPH is essentially putting forth here a theory of generic-generic injury. The idea is that those direct purchasers who purchased only generics were still harmed as a result of Defendants' conduct because

> members of the proposed Truvada and Atripla Classes that purchased the generic during Teva's de-facto exclusivity period paid more for the generics they purchased than they would have in the but-for world. This is because in the actual world, these members of the proposed Truvada and Atripla Classes could only purchase from Teva, and in the but-for world, they would have benefited from the price-based competition between at least five manufacturers of generic Truvada and three manufacturers of generic Atripla that would have entered simultaneously as early as February 2018 in the but-for world.

Lamb Reply Rpt. ¶ 52.

Gilead argues that the Court should reject the generic-generic theory because it essentially espouses an "umbrella theory" – *i.e.*, Defendants' alleged anticompetitive conduct

> created a "price umbrella" under which **non-conspiring** competitors of the defendants raised their . . . prices to an artificial level at or near the [supracompetitive] price. . . .
>
> The umbrella theory is essentially a consequential damages theory. It seeks to hold [defendants] liable for harm allegedly flowing from the illegal conduct even though the . . . defendants received none of the illegal gains and were uninvolved in their competitors' pricing decisions.

In re Coordinated Pretrial Proceedings in Petroleum Prods. Antitrust Litig., 691 F.2d 1335, 1338-39 (9th Cir. 1982) (emphasis added).

In *Petroleum Products*, the Ninth Circuit rejected the umbrella theory in a price-fixing case. It noted that,

> [i]n *Mid-West Paper* [*Products Co. v. Continental Group, Inc.*, 596 F.2d 573 (3d Cir. 1979)], the Third Circuit found the umbrella claim before it analogous to the pass-on issue involved in *Illinois Brick* because "in both situations the plaintiff seeks to recover for higher prices set by, and paid by it to, parties other than the defendants." Given the fact that numerous factors influence a firm's pricing decisions, the court concluded that an umbrella claim is necessarily conjectural and speculative in nature. Moreover, ascertaining how and why a competitor of the defendant charged a certain price would mire the court in a complex economic proceeding of the type *Illinois Brick* sought to prevent. The spectre of complicated, speculative proceedings combined with the potential for ruinous recoveries, well in excess of defendants' illegally earned profits, led the court to hold that purchasers from competitors of price-fixing defendants may not seek damages under an umbrella theory of liability.

Id. at 1339.

The Ninth Circuit went on to hold that "the limitations recognized in *Illinois Brick* bar[red] the umbrella claims" being brought by the plaintiffs, particularly because of the *multi-tiered* distribution at issue in the case. *Id.* at 1340. The court then stated that, "wholly apart from the problems of pass-on and double recovery [identified in *Illinois Brick*]," the plaintiffs' claims were problematic because they were "unacceptably speculative and complex." *Id.* at 1340-41.

> Under an umbrella theory, the result of any attempt to ascertain with reasonable probability whether the non-conspirators' prices resulted from the defendants' purported price-fixing conspiracy or from numerous other pricing considerations would be speculative to some degree. *When the fact of a multi-tiered distribution system is imposed upon the above complex set of variables, the obstacles to intelligent inquiry become nearly insurmountable*. The causal effect

> of each pricing decision would have to be pursued through the chain of distribution. Not only would we be required to speculate that plaintiffs were injured solely as the result of umbrella pricing, but also we would be required to sanction complex judicial inquiry into the pricing decisions of sellers remote from plaintiffs. We decline to do either, and accordingly hold that under the facts of this case, application of an umbrella theory is unwarranted.

Id. at 1341 (emphasis added).

In response, KPH argues that Gilead's reliance on *Petroleum Products* is misplaced because *Petroleum Products* is a price-fixing case whereas, here, the case concerns the exclusion of competition. KPH cites in support *Modafinil*, 837 F.3d at 238. There, the Third Circuit noted as follows:

> Defendants' argument that *Mid-West Paper* [the Third Circuit decision referenced in *Petroleum Products*] means that a **customer of a non-defendant** cannot have antitrust standing is an oversimplification. *Mid-West Paper* reached its result because it wanted to ensure that only those who are most directly harmed by the anticompetitive conduct can sue to remedy the antitrust violation. When, as in *Mid-West Paper*, the anticompetitive conduct is price-fixing, the only customers who will have antitrust standing are the **direct customers of the conspiracy members**. The case before us is not about price-fixing. It is, instead, a case about market exclusion, as it concerns conduct that prevents a competitive market from forming at all. In such a scenario, **all market customers** should have antitrust standing to sue those engaged in the allegedly anticompetitive conduct because all suffer equally from the foreclosure of choice.

Id. at 264-65 (emphasis added). In *In re Loestrin 24 FE Antitrust Litigation*, No. MDL No. 13-2472-WES-PAS, 2019 U.S. Dist. LEXIS 118308 (D.R.I. July 2, 2019), the court reached a similar conclusion: although one group of direct purchasers never purchased the brand drug from defendants and made all their relevant purchases from a nondefendant generic manufacturer, the court still held that "Defendants' alleged unlawful conduct is plainly the proximate cause of the Generic-Only Purchasers' alleged antitrust injury." *Id.* at *32.

The Areeda and Hovenkamp antitrust treatise also supports KPH's position. The treatise notes that, "[w]hen some competitors conspire to limit their output and bring about higher market prices, their **nonconspiring** rivals might [*e.g.*,] maintain their previous output and thereby enjoy higher prices [or] increase their output a bit and thus enjoy somewhat higher prices as well as more volume." Areeda & Hovenkamp, Antitrust Law ¶ 347 (5th ed.) (emphasis added). In either

case, "the conspiracy caused market prices to rise and thereby to injure consumers, regardless of whether they purchased from the conspirators or from their innocent rivals." *Id.* (emphasis in original).

> May those who purchased from innocent suppliers at the inflated umbrella price recover from the conspirators? These purchasers' own suppliers are not liable, for they have violated no antitrust law, notwithstanding their excess profits resulting from the umbrella price. Because purchasers from the innocent suppliers pay a monopoly overcharge just as certainly as if they had bought from the conspirators, their injury can be compensated only by allowing them to sue the competitors.

Id.

Areeda and Hovenkamp recognized that there may be concerns here regarding causation and proof of damages. For instance, "the conspirators may object to the fairness of extracting from them damages based on the sales of nonconspirators – sales that profited the latter, not the former"; however, the treatise did not find this argument compelling because "[s]uch liability is no less just than the joint and several liability that *each* conspirator bears for *all* the damage caused by all the conspirators collectively." *Id.* (emphasis in original). That being said, the treatise did go on to state that there could be a point where causation and proof of damages would be too speculative – *e.g.*, "the umbrella theory of standing makes a great deal of sense when a cartel and its competitors sell the same product, and the competitor is able to ride its price up on the cartel's price increase" but, "[a]s soon as there is significant differentiation [between products], . . . this simplicity vanishes." *Id.*

Gilead suggests that, at the very least, the class definitions should be limited in the same way as the EPPs' class definitions – *i.e.*, to purchases of (1) brand drugs or (2) generic drugs sold by *Teva* specifically (and not any generic manufacturer).[24] To the extent Gilead is arguing that the

[24] To be clear, Gilead still argues that even generic drugs purchased from Teva should not count. *See* Opp'n at 12 ("Even if KPH tries to argue that certain generic-only purchasers should be in the proposed classes to the extent they purchased from generic manufacturer Teva, that argument equally lacks merit because KPH's Amended Complaint does not name Teva as a Defendant or even as a non-party co-conspirator. . . . And nowhere in the Amended Complaint does KPH allege that Gilead, BMS, or Janssen conspired with Teva as to how Teva ultimately sold and priced its generic products *after* generic entry.") (emphasis in original); *see also* Strombom Rpt. ¶ 36 (indicating the same).

causal connection with respect to generic drugs sold by Teva is stronger, that is probably true. Even if Teva is not considered a *conspiring* competitor, it is alleged to have functioned in a similar manner.

However, just because the causal connection may be clearer with respect to generic drugs sold by Teva does not mean that there is not a causal connection with respect to generic drugs sold by other generic manufacturers. As indicated above, the whole point of Gilead's actions here was to *exclude* generic competition. In contrast to the consequential but indirect conduct of nonconspirator competition in a price-fixing case, the point of the exclusionary practices here was to limit competition – the anticompetitive effect on the marketplace was foreseeable, indeed intended. And unlike *Petroleum Products*, damage based on higher prices paid to any generic manufacturers other than Defendants does not involve the problems of a "multi-tiered distribution system that compounded the calculation of damages which made the obstacles to intelligent inquiry . . . nearly insurmountable." *Petroleum Prods.*, 691 F.3d at 1341.

Moreover, Gilead does not provide any numbers here about how many generic-only direct purchasers made purchases from Teva only as opposed to other generic manufacturers. Presumably, since Teva had exclusivity for a time in the actual world (*i.e.*, upon generic launch), the number who purchased from Teva is not insignificant; in other words, Gilead could not argue that all 50 direct purchasers of generic Truvada should be excluded and all 24 direct purchasers of generic Atripla should be excluded.

c. Complera

For the reasons stated above, the Court rejects Gilead's contention that the numerosity requirement has not been met – at least with respect to Truvada and Atripla. KPH has provided evidence from its expert Dr. Lamb that there are 78 members in the Truvada Class and 51 members in the Atripla Class, and Gilead's argument that there are a number of direct purchasers who should not be counted – in particular, direct purchasers who are likely opt-outs and generic-only direct purchasers – is not persuasive. There are still over 40 members in each class. *See Jordan*, 669 F.2d at 1319 (indicating that 40 class members is generally sufficient to meet the numerosity requirement); *Tait*, 289 F.R.D. at 473 (stating that "[a] proposed class of at least forty

members presumptively satisfies the numerosity requirement").

This still leaves, however, the Complera Class, which has only 25 members, even under Dr. Lamb's count. Because this is a more modest class size, the Court considers "'other factors' bearing upon the feasibility and convenience of joinder," such as "'the geographical diversity of class members, the ability of individual claimants to institute separate suits, and whether injunctive or declaratory relief is sought,' as well as the ability to identify and locate class members." *A.B.*, 30 F.4th at 836. In the instant case, the critical factors are those addressed below.

- *Geographical diversity of class members.* The 25 members of the Complera Class appear to be dispersed throughout the country (most of them east of the Mississippi River).[25] *See* Lamb Rpt., App. C.3 (map of the United States reflecting locations of 24 out of the 25 class members). This weighs against the practicability of joinder. *See* 1 Newberg and Rubenstein on Class Actions § 3:12 (explaining that "geographic dispersion of class members cuts in favor of certification as joinder of all members of a dispersed class is likely less practicable than joinder of all members of a similarly sized class residing in one neighborhood or working in one workplace"); 5 Moore's Fed. Prac. – Civ. § 23.22[1][d] (stating that "[w]ide geographic dispersion of class members supports a finding of impracticability of joinder"; thus, "a relatively small class may be sufficiently numerous when the added factor of geographic dispersion contributes to making joinder impracticable").
- *Ability of individual claimants to institute separate suits.*[26] The members of the

[25] Because the 25 class members are identifiable and locatable, joinder is practicable. *See* 5 Moore's Fed. Prac. – Civ. § 23.22[1][f] (2022) ("If the class members cannot be readily identified or located by the parties before the court, then joinder of all class members is more likely to be impracticable. Conversely, joinder is more likely to be found to be practicable if the identity and addresses of the class members are readily ascertainable.").

[26] Some circuit courts have held that the ability of a class member to bring an individual suit is not a relevant consideration – *i.e.*, the "binary choice" is that of "a class action versus joinder of all interested parties." *Modafinil*, 837 F.2d at 253 (emphasis in original); *see also id.* at 258 (holding that district court erred in focusing on "whether the individual plaintiffs could have brought their

Complera Class, in general, appear to be companies with significant annual revenues. Although Gilead does not provide information about annual revenues for each of the 25 members in the class, it appears that at least 22 of them (including Albertsons, CVS, Rite Aid, Kroger, and Walgreen which have already filed individual suits) have annual revenues in excess of $37 million. *See* Strombom Rpt. ¶ 48 & Fig. 6 (chart showing historical annual revenues).[27] It also appears that most – but not all – of the class members have significant damages (brand-generic injury), especially when treble damages are taken into account. *See* Strombom Rpt. ¶ 50 & Fig. 7 (indicating that most class members have over $10 million in damages, when treble damages are included; but also reflecting that a handful have less than $300,000 in treble damages). The bulk of the damages seem to have been claimed by 3 companies: AmerisourceBergen, McKesson, and Cardinal Health. *Cf.* Strombom Rpt. ¶ 48 (indicating that, when "improper" class members are excluded, these 3 companies "accounted for approximately *94 percent* of the purchases of brand Complera") (emphasis added). These circumstances suggest that joinder is, in fact, practicable and/or that other putative class members could institute separate suits. *See* 5 Moore's Fed. Prac. – Civ. § 23.22[1][e] (noting that, "if each individual class member has a considerable financial stake in the dispute, then individual suits are more likely and joinder is not likely to be impracticable"). To the extent there are a few class members who do not have significant damages, they could still join together to file suit or join this lawsuit. *See Modafinil*, 837

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own, individual suits" because the numerosity requirement "does not envision the alternative of individual suits; it considers only the alternative of joinder"); *accord In re Zetia (Ezetimibe) Antitrust Litig.*, 7 F.4th 227, 235 (4th Cir. 2021) (stating that, "[w]hen analyzing the judicial-economy factor . . . , the district court should consider whether judicial economy favors *either* a class action *or* joinder[;] [o]therwise, the judicial-economy factor would always favor class certification, which is simpler to manage than individual lawsuits") (emphasis in original). Gilead asserts that this authority should be followed.

[27] It is not clear what the historical annual revenues of H.D. Smith, HEB, and Valley Wholesale are; they are not represented on Figure 6. H.D. Smith and Valley Wholesale appear to have been acquired by AmerisourceBergen. *See* Opp'n at 13; Strombom Rpt. ¶ 50 & Fig. 7 (chart showing Dr. Lamb's estimated brand-generic overcharges).

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F.3d at 259 (noting that there were 6 class members with "claims below $1 million each[;] [w]hile it may be uneconomical for these claims to be pursued in individual litigation, there has been no showing that it would be uneconomical for these six class members to be individually joined as parties in a traditional lawsuit").

On balance, the Court is persuaded that the relevant factors weigh against KPH on the numerosity requirement. As Gilead points out, the Third Circuit noted in *Modafinil*: "[We] have never seen a class action where three class members [out of 22-25 total], each with billions of dollars at stake and close to 100% of the total value of class claims between them, have been allowed to sit on the sidelines as unnamed class members." *Modafinil*, 837 F.3d at 259.

In response, KPH contends that it is telling that more than two-thirds of the class members, including the "Big 3," have *not* filed suit – and asserts that they have not done so because of a fear of retaliation. *See* 5 Moore's Fed. Prac. – Civ. § 23.22[1][3] (noting that "courts will be more likely to find impracticability of joinder if fear or retaliation or prejudice could deter individual class members from bringing suit"). Retaliation, however, seems speculative and highly questionable. If most class members had significant purchases, then, if anything, Gilead would have an interest in *not* retaliating because of its own interest in preserving those relationships.

Relying on *Solodyn*, KPH also suggests that there are

> "formidable business realities and legal hurdles standing in the way of [joinder in a common suit]." The competitive relationship among some class members serves "as a significant business obstacle" to joinder. To illustrate this, [the *Solodyn*] DPPs conducted an empirical analysis of approximately 20,000 federal case filings from the last fifteen years involving one or more members of this class, finding that in only five cases – were these members plaintiffs in pharmaceutical antitrust cases that were *not* class actions. DPPs [further] explain that such cases are so infrequent because the nature of the litigation makes ascertaining damages difficult at the outset and many cases mirror this one, where DPPs have demonstrated that approximately half of the putative class members have negative value claims.[28] Such cases are the reason why the class action mechanism exists: there is no incentive for these parties to join in light of the litigation costs as compared to the damages at stake.

[28] "A negative value claim is a claim[] that could not be brought on an individual basis because the transaction costs of bringing an individual action exceed the potential relief." *Modafinil*, 837 F.3d at 257 n.21.

Solodyn, 2017 U.S. Dist. LEXIS 170676, at *24-25 (emphasis added). But the analysis in *Solodyn* is arguably problematic or at least not applicable to the instant case. First, it is not clear why a competitive relationship among class members would be a significant obstacle to joinder. The fact that there has been joinder in only a limited number of cases in the past may simply reflect a lack of interest in bringing suit because of an ability to pass on overcharges downstream. Second, to the extent overcharges were not passed on downstream, the asserted damages of most class members is substantial enough such that there is an incentive to sue even if antitrust damages might be hard to prove. Third, while there appear to be some class members here with small or negative value claims, it does not seem to be a notable number. Putative class members, if the class is not certified, could still be *joined* to this lawsuit which would allow them to piggyback on the efforts already expended in the litigation.[29]

Finally, to the extent KPH relies on *Lidoderm*, that case is factually distinguishable. There,

> the number of class members – 52 at a minimum – makes joinder impracticable, [and] other relevant factors support this conclusion. One is the judicial economy from proceeding as a class action, which is especially true since 44 DPPs [*i.e.*, the vast majority] have claims worth less than it would realistically cost to litigate an expert- and discovery-intensive case like this one. These smaller DPPs also may not have the market-power security to challenge defendants when they need to negotiate to purchase drugs from these same entities in the future. The wide geographic dispersion of the DPPs also weighs against joinder. Finally, that the "Big Three" DPP class members (McKesson, Cardinal Health, and AmerisourceBergen) account for 86% of the purchases only heightens the conclusion as to impracticality of joinder given the smaller-size of the other DPPs' claims.

Lidoderm, 2017 U.S. Dist. LEXIS 24097, at *72-73. Judge Orrick went on to state that *Modafinil* was not controlling in his case because "[t]here are far more DPP class members here than in that case (53 versus 22) and the market concentration of the larger players [the same Big 3] is less

[29] To the extent KPH suggests that it is too late in the day for joinder to take place, the Third Circuit held in *Modafinil* that "the late stage of litigation is not by itself an appropriate consideration to take into account as part of the numerosity analysis." *Modafinil*, 837 F.3d at 254. In any event, it is not clear to the Court that joinder of some direct purchasers to the case would not be possible, even at this relatively late stage of the proceedings.

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significant (97% versus 86%)." *Id.* at *73. To the extent judicial economy is a consideration, there is no showing here that joinder would result in a greater burden on the Court than class certification given the concentration of sales in three large entities.

Accordingly, the Court concludes that certification of the Complera Class is not warranted because KPH has not shown that the Rule 23(a) numerosity requirement has been satisfied. However, the numerosity requirement has been met for the Truvada and Atripla Classes, and therefore, the Court continues to evaluate the Rule 23(b)(3) requirements as to those Classes.

B. Rule 23(b) Requirements

Gilead argues that, even if the Court considers only the Truvada and Atripla Classes, there is a predominance problem: specifically, KPH cannot prove antitrust injury or impact by common evidence because there is a significant number of uninjured class members and thus individualized inquiries will predominate.

Gilead does not challenge the brand-generic injury claimed by KPH but does contest the generic-generic injury asserted. The gist of Gilead's argument is as follows:

- As noted above, there are 78 total members in the Truvada Class and 51 total members in the Atripla Class.
- Out of the 78 Truvada class members, 50 made generic-only purchases; out of the 51 Atripla class members, 24 made generic-only purchases.
- According to Gilead, most of these generic-only purchasers ended up paying *less* for the generics in the actual world compared to the average prices of the generics in the but-for world. *See* Opp'n at 25; Strombom Rpt. ¶ 74. Specifically, Gilead claims that (1) 38 out of the 50 generic-only purchasers in the Truvada Class paid less than the average price in the but-for world (*i.e.*, **42%** of the 78 total members in the Truvada Class), and (2) 13 out of the 24 generic-only purchasers in the Atripla Class paid less than the average price in the but-for world (*i.e.*, **25%** of the 51 total class members). *See* Opp'n at 25-26; Strombom Rpt. ¶ 77. Gilead adds that these purchasers (who purportedly paid less) made their purchases after March 2021 – *i.e.*, after *mass* generic entry ("the simultaneous entry of multiple generic

competitors that Dr. Lamb contends is the primary cause of average generic prices declining"). Strombom Rpt. ¶ 74 (criticizing Dr. Lamb for "not fully explain[ing] why the entities that exclusively purchased after mass generic injury are injured").

Dr. Lamb's reply report, however, sufficiently addresses this issue.[30] According to Dr. Lamb, Gilead's expert, Dr. Strombom, reached this conclusion based on a flawed comparison. Dr. Lamb "calculated a but-for price for each of the HIV drugs at issue using the *IQVIA NSP* data[[31]] and compared those prices to the actual prices in the *IQVIA NSP* to determine the amount of aggregate overcharges paid by members of the proposed Classes." Lamb Rebuttal Rpt. ¶ 45 (emphasis added; adding that, "[i]n using the IQVIA NSP data to measure *both* actual and but-for prices, my analysis effectively washed out the effect of any differences between the IQVIA NSP data and the transaction data") (emphasis added). But Dr. Strombom did not make this same comparison. Rather he compared "the but-for generic Truvada and Atripla prices based on the *IQVIA NSP data*" to "the actual gross prices paid by individual proposed Class members in the *transaction-level* data."[32] Lamb Rebuttal Rpt. ¶ 44 (emphasis added). Accordingly, Dr. Strombom failed to make an "apples-to-apples comparison. His comparisons fail to control for the differences between the IQVIA NSP data and the transaction-level data." Lamb Reply Rpt. ¶ 45.

Dr. Lamb went on to make a comparison between (1) but-for *transaction-level* prices and (2) actual net *transaction-level* prices. *See, e.g.*, Lamb Rebuttal Rpt. ¶ 47 (noting that he "replace[d] the IQVIA NSP but-for price with a but-for price calculated from the transaction-level

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[30] As an initial matter, Dr. Lamb criticizes this attack on the basis that he was not using the but-for price to assess whether all or nearly all class members were injured; rather, he was using the but-for price to measure class-wide aggregate overcharges only. *See* Lamb Reply Rpt. ¶ 46. However, Dr. Lamb also goes on to explain why the argument is substantively incorrect.

[31] NSP is yet another data product offered by IQVIA.

[32] In his report, Dr. Strombom indicates that he purposefully chose gross prices (*i.e.*, prices before discounts to direct purchasers) in order to be conservative. *See* Strombom Rpt. ¶ 78 ("[T]he IQVIA data includes some but not all discounts paid to the direct purchaser by a manufacturer. By relying on the gross price from the generic manufacturer transaction data, I am not accounting for any discounts to direct purchasers. That is, I find that for many of the putative class members, their gross price before discounts is lower than Dr. Lamb's average but-for price. Adjusting individual purchasers' generic prices to *include* discounts would reduce the generic prices paid by direct purchasers and likely result in additional uninjured putative class members.").

data"). With this apples-to-apples comparison, Dr. Lamb reaffirmed that "generic-only purchasers were injured in that they paid a higher price for the generic Truvada [or Atripla] they purchased in the actual world than they would have in the but-for world."[33] Lamb Reply Rpt. ¶ 47; *see also* Lamb Reply Rpt. ¶ 48.

Dr. Lamb indicates that it is not surprising that generic-only purchasers have suffered injury even after mass generic entry because, even after mass generic entry, it takes some time for prices to "bottom out." *See* Lamb Reply Rpt. ¶ 59 ("[S]tudies show that even following mass generic entry, generic prices continue to decline gradually for some time."); Lamb Reply Rpt. ¶ 60 ("This finding in the academic literature is consistent with what manufacturers of generic Truvada and generic Atripla expected to happen when generic Truvada and generic Atripla entered the market."); Lamb Reply Rpt. ¶ 64 ("The forecast documents produced by the generic manufacturers . . . are consistent with the actual experience of the markets for Truvada and Atripla following generic entry, which shows that the prices of generic Truvada and Atripla in the IQVIA NSP data have continued to fall even as the number of generic manufacturers remained constant.").[34]

Gilead protests still that Dr. Lamb's analysis is flawed because "many generic-only purchasers paid *flat* gross prices" after mass generic entry in the actual world – which contradicts Dr. Lamb's assumption that "entities would pay decreasing prices in the but-for world." Strombom Rpt. ¶ 75 (emphasis added); *see also* Opp'n at 26. But Dr. Lamb adequately addresses this criticism in his reply report. For example:

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[33] In his reply report, Dr. Lamb notes that reliance on transaction-level data is problematic because it is not complete. *See* Lamb Rebuttal Rpt. ¶ 43 (stating that, "[w]ithout complete transaction-level data from the generic manufacturers, including updated data on price adjustments, any but-for generic price calculated from the transaction-level data would be artificially high"; nevertheless, even making a comparison of the actual world and the but-for world with transaction-level data, "all or nearly all generic-only purchasers were injured").

[34] In his report, Dr. Lamb underscores that "analysis of the IQVIA NSP data [is] just one piece of common evidence" in support of his "conclusion that all or nearly all members of the proposed Classes were injured." Lamb Reply Rpt. ¶ 34. He also relied on "(1) published research concerning the effects of generic competition in pharmaceutical markets; [and] (2) Defendants' and Janssen's documents and forecasts regarding the effects of generic competition in the markets for HIV drugs." Lamb Reply Rpt. ¶ 34; *see also* Lamb Reply Rpt. ¶ 74 (discussing common evidence).

(1) Dr. Strombom is relying on transaction-level data produced by generic manufacturers and "many of [these] productions cover limited time periods [and] with little overlap across them." Lamb Reply Rpt. ¶ 70.

(2) Dr. Strombom did not consider data from three generic manufacturers. *See* Lamb Reply Rpt. ¶ 70.

(3) Dr. Strombom considered prices over a seven or nine-month period only, but "the IQVIA NSP data demonstrate that generic prices have continued to decline through early 2022 [*i.e.*, well after mass generic entry]." Lamb Reply Rpt. ¶ 70; *see also* Lamb Reply Rpt. ¶ 64 (stating that "the prices of generic Truvada and Atripla in the IQVIA NSP data have continued to fall even as the number of generic manufacturers remained constant").

(4) Even if there were flat prices for generic Truvada and Atripla in the actual world, that does not mean there was no injury in the but-for world. "[I]n the but-for world with earlier generic entry, generic prices would have launched in a market with a lower branded price. The lower initial brand price at the time of but-for generic entry means that the generic would have launched at a lower price than it did in the actual world and that the generic price would have continued to fall over time as generic manufacture[r]s continue to compete against each other." Lamb Reply Rpt. ¶ 72.

(5) Using the apples-to-apples comparison, there was injury. *See* Lamb Rebuttal Rpt. ¶ 73.

Dr. Lamb's analysis is credible and more complete and is entitled to greater weight for purposes of this motion than that of Dr. Strombom. Accordingly, KPH has satisfied the predominance requirement of Rule 23(b)(3) for each of the Truvada and Atripla Classes. Likewise, the superiority requirement of Rule 23(b)(3) has been met.

C. Class Certification

For the foregoing reasons, the Court certifies two of the three Damages Classes:

(1) Truvada Class: "All persons or entities in the United States and its territories who

purchased Truvada or generic Truvada directly from any of Defendants or any brand or generic drug manufacturer from February 1, 2018, until the date of the class certification order." DPP Mot. at 1-2.

(2) Atripla Class: "All persons or entities in the United States and its territories who purchased Atripla or generic Atripla directly from any of Defendants or any brand or generic drug manufacturer from February 1, 2018, until the date of the class certification order." DPP Mot. at 2.

The Court appoints KPH as the class representative for each of the above Classes and further appoints as counsel for the Classes the current counsel representing KPH.

The Court orders the parties to meet and confer regarding the content and timing of a class notice. The parties shall report back on their efforts within two weeks of the date of this order.

D. *Daubert* Motion

With respect to the DPP motion for class certification, Gilead filed a *Daubert* motion with respect to only one DPP expert, Dr. Lamb. In his expert report, Dr. Lamb provided opinions regarding, *inter alia*, antitrust injury/impact. In its *Daubert* challenge, Gilead makes a number of arguments, many of which replicate arguments made in the opposition to the DPP motion for class certification. Similar to above, the Court concludes that Dr. Lamb's opinions are sufficiently reliable such that they are admissible and may be considered for purposes of the class certification motion. Gilead's challenges to Dr. Lamb go more to the weight of his opinions rather than their admissibility.

1. Generic-Generic Injury

Gilead argues that Dr. Lamb's opinions regarding generic-generic injury to the Truvada and Atripla Classes are unreliable because most generic-only purchasers who purchased *after mass generic entry* were not injured at all.

Although Gilead has a basis to cross-examine Dr. Lamb on this issue, it has not shown that his opinions regarding injury even after mass generic entry are not reliable. This issue has largely been addressed above. In short, Dr. Lamb has cited sources to support his position that, even after mass generic entry, generic prices decline, if only because it takes some time for generic prices to

bottom out. His sources include academic studies, forecast documents of generic manufacturers (for Truvada and Atripla specifically), and the actual data for prices of generic Truvada and Atripla. *See, e.g.*, Lamb Reply Rpt. ¶¶ 59-68. Dr. Lamb and Dr. Strombom (the defense expert) appear to disagree about whether there was a decline in the prices of generic Truvada and Atripla for various reasons, including because Dr. Strombom did an apples-to-oranges comparison (IQVIA data to transaction-level data) rather than an apples-to-apples comparison (IQVIA data to IQVIA data, or transaction-level data to transaction-level data). Furthermore, Dr. Strombom's transaction-level data covered only a limited period of time. Finally, even if there was no decline in prices after mass generic injury, there could still be injury in the but-for world: "[I]n the but-for world with earlier generic entry, generic prices would have launched in a market with a lower branded price. The lower initial brand price at the time of but-for generic entry means that the generic would have launched at a lower price than it did in the actual world and that the generic price would have continued to fall over time as generic manufacture[r]s continue to compete against each other." Lamb Reply Rpt. ¶ 72. This is a rational analysis.

2. <u>"Big 3" Purchasers of Generic Truvada and Atripla</u>

Gilead also argues that Dr. Lamb's opinions related to Truvada and Atripla are unreliable because he did not "conduct a sensitivity analysis" to determine whether "the trends he observed in the average prices of generic Truvada and Atripla were consistent with the price trends experienced by individual generic purchasers." Daubert Mot. at 7. According to Gilead, had he done so then he would have been that "the experience of individual purchasers significantly deviates from and largely conflicts with the 'average' price trends observed by Dr. Lamb" because over 90% of the purchases of brand/generic Truvada and brand/generic Atripla were made by just three putative class members – *i.e.*, the "Big 3" (Cardinal Health, McKesson, and AmerisourceBergen). *See* Daubert Mot. at 7. In other words, the average price essentially represents what the Big 3 paid and "do not accurately represent the prices paid by other wholesalers in the proposed classes." Daubert Mot. at 8; *see also* Strombom Rpt. ¶ 59 ("[T]he 'class-wide' averages are essentially the averages for the 'Big 3' wholesalers . . . since they accounted for nearly 91 percent of the class purchases of brand Truvada and the generic version or

Truvada, approximately 95 percent of the class purchases of brand Atripla and the generic version of Atripla, and over 94 percent of the class purchases of brand Complera.").

But as Dr. Lamb responds in his reply report:

> Dr. Strombom confuses an analysis of class-wide damages with a methodology for allocating class-wide damages. Whether or not the characteristics of any given proposed Class member would cause them to receive a disproportionately large amount of damages relative to the rest of the proposed Classes as a result of the alleged misconduct has no bearing was to whether all or nearly all proposed Class members were injured as a result of the alleged misconduct, whether such injury can be proven with common evidence, and whether aggregate class-wide damages can be measured using common evidence.

Lamb Reply Rpt. ¶ 22. As indicated above in conjunction with the EPPs' motion, the Court is inclined to have a bifurcated trial where aggregate damages would be dealt with in Phase I (along with liability and injunctive relief), and allocation of damages would be dealt with in Phase II.

3. Price Negotiations for Generic Truvada and Generic Atripla

Finally, Gilead criticizes Dr. Lamb's opinions on Truvada and Atripla as being unreliable because he did not take into account that the generic prices paid by wholesalers are variable, *i.e.*, subject to individual price negotiations between generic manufacturers and wholesalers. *See* Daubert Mot. at 8; Strombom Rpt. ¶ 31.

But again, Dr. Lamb sufficiently addresses this in his reply report: (1) "these discounts and negotiations would be present in both the actual and but-for world," Lamb Reply Rpt. ¶ 20; and (2) "the fact that there is variation in the prices paid by direct purchasers due to the differences in discounts and contracting terms, or the fact that other differences exist between direct purchasers, is irrelevant to assessing impact." Lamb Reply Rpt. ¶ 20. In other words, just because "some proposed Class members were able to negotiate lower prices than other proposed Class members does not mean that they were able to avoid injury. [And] Dr. Strombom ignores the fact that the discounts he identifies as contributing to pricing variation are calculated off of the same reference prices." Lamb Reply Rpt. ¶ 25. Dr. Lamb concluded that, "[f]or all of the proposed Class members that purchased branded Truvada and/or branded Atripla, the actual individual net prices they paid [including the lowest] were significantly higher than the price they would have paid for

generic Truvada and/or generic Atripla in the but-for world." Lamb Reply Rpt. ¶ 27. Again, Dr. Lamb's conclusions are reasonable and rest on a sufficient basis – sufficient to survive *Daubert*.

V. CONCLUSION

For the reasons stated above, both the EPPs and the DPPs' motions for class certification are granted in part and denied in part. With respect to the EPPs, the Court certifies three Damages Classes (Truvada, Atripla, and Complera) and three Injunctive Relief Classes (Evotaz, Prezcobix, and cART Foundation Drugs). For the Damages Classes, certification is for fewer than the 35 repealer states identified in the EPP motion for class certification. With respect to the DPPs, the Court certifies two Damages Classes (Truvada and Atripla).

As noted above, the Court orders the parties to meet and confer regarding various issues related to class certification and to report back within two weeks of the date of this order.

Finally, the Court orders that Part III.D.1.a of this order temporarily be filed under seal. The parties shall meet and confer to determine which specific parts of this section should be filed under seal. The Court instructs the parties that, given the significance of this order, it expects any sealing request to be narrowly tailored. The parties shall file their sealing request within two weeks of the date of this order.

This order disposes of Docket Nos. 692 and 694.

IT IS SO ORDERED.

Dated: September 27, 2022

EDWARD M. CHEN
United States District Judge

United States District Court
Northern District of California